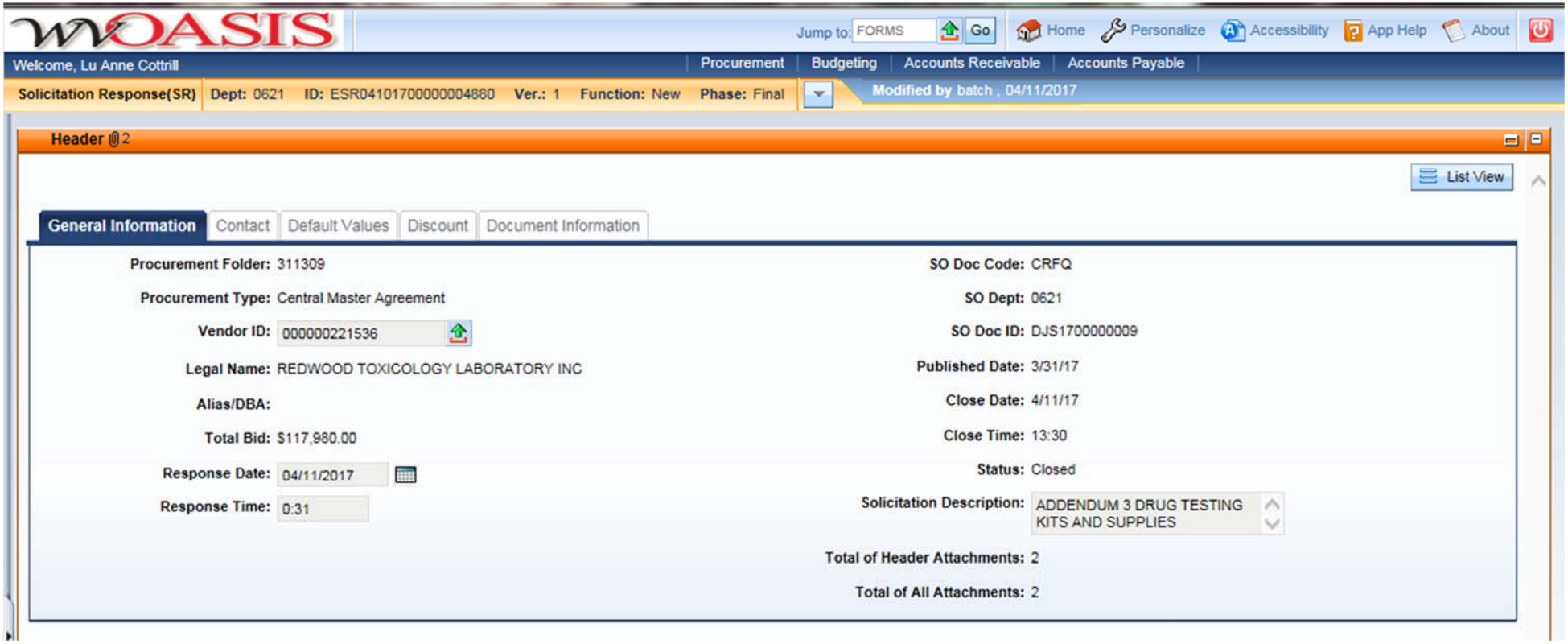
The following documentation is an electronically-submitted vendor response to an advertised solicitation from the *West Virginia Purchasing Bulletin* within the Vendor Self-Service portal at ***wvOASIS.gov***. As part of the State of West Virginia's procurement process, and to maintain the transparency of the bid-opening process, this documentation submitted online is publicly posted by the West Virginia Purchasing Division at ***WVPurchasing.gov*** with any other vendor responses to this solicitation submitted to the Purchasing Division in hard copy format.


WVOASIS
Jump to: FORMS Go
Home
Personalize
Accessibility
App Help
About
Welcome, Lu Anne Cottrill
Procurement
Budgeting
Accounts Receivable
Accounts Payable
Solicitation Response(SR) Dept: 0621 ID: ESR04101700000004880 Ver.: 1 Function: New Phase: Final
Modified by batch , 04/11/2017
Header 2
List View
General Information
Contact
Default Values
Discount
Document Information
Procurement Folder: 311309
Procurement Type: Central Master Agreement
Vendor ID: 000000221536
Legal Name: REDWOOD TOXICOLOGY LABORATORY INC
Alias/DBA:
Total Bid: $117,980.00
Response Date: 04/11/2017
Response Time: 0:31
SO Doc Code: CRFQ
SO Dept: 0621
SO Doc ID: DJS1700000009
Published Date: 3/31/17
Close Date: 4/11/17
Close Time: 13:30
Status: Closed
Solicitation Description: ADDENDUM 3 DRUG TESTING KITS AND SUPPLIES
Total of Header Attachments: 2
Total of All Attachments: 2

Purchasing Division
2019 Washington Street East
Post Office Box 50130
Charleston, WV 25305-0130

State of West Virginia
Solicitation Response

Proc Folder : 311309

Solicitation Description : ADDENDUM 3 DRUG TESTING KITS AND SUPPLIES

Proc Type : Central Master Agreement

Date issued	Solicitation Closes	Solicitation Response	Version
	2017-04-11 13:30:00	SR 0621 ESR04101700000004880	1

VENDOR

000000221536

REDWOOD TOXICOLOGY LABORATORY INC

Solicitation Number: CRFQ 0621 DJS1700000009

Total Bid : $117,980.00 **Response Date:** 2017-04-11 **Response Time:** 00:31:03

Comments:

FOR INFORMATION CONTACT THE BUYER

Crystal Rink

(304) 558-2402
crystal.g.rink@wv.gov

Signature on File **FEIN #** **DATE**

All offers subject to all terms and conditions contained in this solicitation

Line	Comm Ln Desc	Qty	Unit Issue	Unit Price	Ln Total Or Contract Amount
1	13 Panel Urine Test Kit	8000.00000	EA	$5.050000	$40,400.00

Comm Code	Manufacturer	Specification	Model #
46151606			

Extended Description : 13 Panel Urine Test Kit

Comments: See Pricing Page Exhibit A for more details, including optional cup item. Five business days for RTL inventory product (i.e. iCup) or DrugCheck cup once stocked in inventory; five days or more for DrugCheck custom cups.

Line	Comm Ln Desc	Qty	Unit Issue	Unit Price	Ln Total Or Contract Amount
2	6- Panel Oral Swab Test Kit (Standard)	500.00000	EA	$5.600000	$2,800.00

Comm Code	Manufacturer	Specification	Model #
46151606			

Extended Description : 6- Panel Oral Swab Test Kit (Standard) WV DJS USE

Comments: See Pricing Page Exhibit A for more details, including optional OFDs and prices. Five business days for RTL inventory product (i.e. iScreen OFD, OrAlert, Oratect) or DrugCheck SalivaScan once stocked; five days or more for DrugCheck SalivaScreen custom OFD.

Line	Comm Ln Desc	Qty	Unit Issue	Unit Price	Ln Total Or Contract Amount
3	6- Panel Oral Swab Test Kit (Customizable)	500.00000	EA	$5.600000	$2,800.00

Comm Code	Manufacturer	Specification	Model #
46151606			

Extended Description : 6- Panel Oral Swab Test Kit (Customizable) WV DOC USE

Comments: See Pricing Page Exhibit A for more details, including optional OFDs and prices. Five business days for RTL inventory product (i.e. iScreen OFD, OrAlert, Oratect) or DrugCheck SalivaScan once stocked; five days or more for DrugCheck SalivaScreen custom OFD.

Line	Comm Ln Desc	Qty	Unit Issue	Unit Price	Ln Total Or Contract Amount
4	8 Panel Urine Test Kit (Standard)	600.00000	EA	$2.800000	$1,680.00

Comm Code	Manufacturer	Specification	Model #
85121805			

Extended Description : 8 Panel Urine Test Kit (Standard) WV DJS USE

Comments: See Pricing Page Exhibit A for more details. Five business days for delivery of iCup.

Line	Comm Ln Desc	Qty	Unit Issue	Unit Price	Ln Total Or Contract Amount
5	8 Panel Urine Test Kit (Customizable)	600.00000	EA	$3.720000	$2,232.00

Comm Code	Manufacturer	Specification	Model #
46151606			

Extended Description : 8 Panel Urine Test Kit (Customizable) WV DOC USE

Comments: See Pricing Page Exhibit A for more details, including optional cup item. Five business days for RTL inventory product (i.e. iCup) or DrugCheck cup once stocked; five days or more for DrugCheck custom cups.

Line	Comm Ln Desc	Qty	Unit Issue	Unit Price	Ln Total Or Contract Amount
6	Nicotine Test Only	1200.00000	EA	$1.090000	$1,308.00

Comm Code	Manufacturer	Specification	Model #
46151606			

Extended Description : Nicotine Test Only

Comments: See Pricing Page Exhibit A for more details, including optional Nicotine item. Five business days for RTL inventory product (i.e. Nicotine cassette); five days or more for DrugCheck Nicotine dip.

Line	Comm Ln Desc	Qty	Unit Issue	Unit Price	Ln Total Or Contract Amount
7	Buprenorphine Test Only	800.00000	EA	$0.450000	$360.00

Comm Code	Manufacturer	Specification	Model #
46151606			

Extended Description : Buprenorphine Test Only

Comments: See Pricing Page Exhibit A for more details. Five business days for RTL to deliver from placement of order.

Line	Comm Ln Desc	Qty	Unit Issue	Unit Price	Ln Total Or Contract Amount
8	Laboratory Confirmation Services 8 Panel Urine	2000.00000	EA	$11.000000	$22,000.00

Comm Code	Manufacturer	Specification	Model #
46151606			

Extended Description : Laboratory Confirmation Services 8 Panel Urine (Price Per Drug)

Comments: 3 to 4 business days from receipt of specimen at lab for creatinine screen and subsequent confirmation test completion and result delivery.

Line	Comm Ln Desc	Qty	Unit Issue	Unit Price	Ln Total Or Contract Amount
9	Laboratory Confirmation Services 13 Panel Urine	2000.00000	EA	$11.000000	$22,000.00

Comm Code	Manufacturer	Specification	Model #
46151606			

Extended Description : Laboratory Confirmation Services 13 Panel Urine(Price Per Drug)

Comments: 3 to 4 business days from receipt of specimen at lab for creatinine screen and subsequent confirmation test completion and result delivery.

Line	Comm Ln Desc	Qty	Unit Issue	Unit Price	Ln Total Or Contract Amount
10	EtG and EtS Testing (All Inclusive)	2000.00000	EA	$10.950000	$21,900.00

Comm Code	Manufacturer	Specification	Model #
46151606			

Extended Description : EtG and EtS Testing (All Inclusive)

Comments: Negative screen results will be reported within 24-48 hours of receipt of specimen at lab. Specimens needing confirmation will take an additional 48 to 72 hours.

Line	Comm Ln Desc	Qty	Unit Issue	Unit Price	Ln Total Or Contract Amount
11	MRO or Lab Rep As Expert Witness	5.00000	HOUR	$100.000000	$500.00

Comm Code	Manufacturer	Specification	Model #
46151606			

Extended Description : MRO or Lab Rep As Expert Witness (Price Per Hour)

Comments: Toxicologist in-court expert testimony fee (no MRO).

REDWOOD TOXICOLOGY LABORATORY™

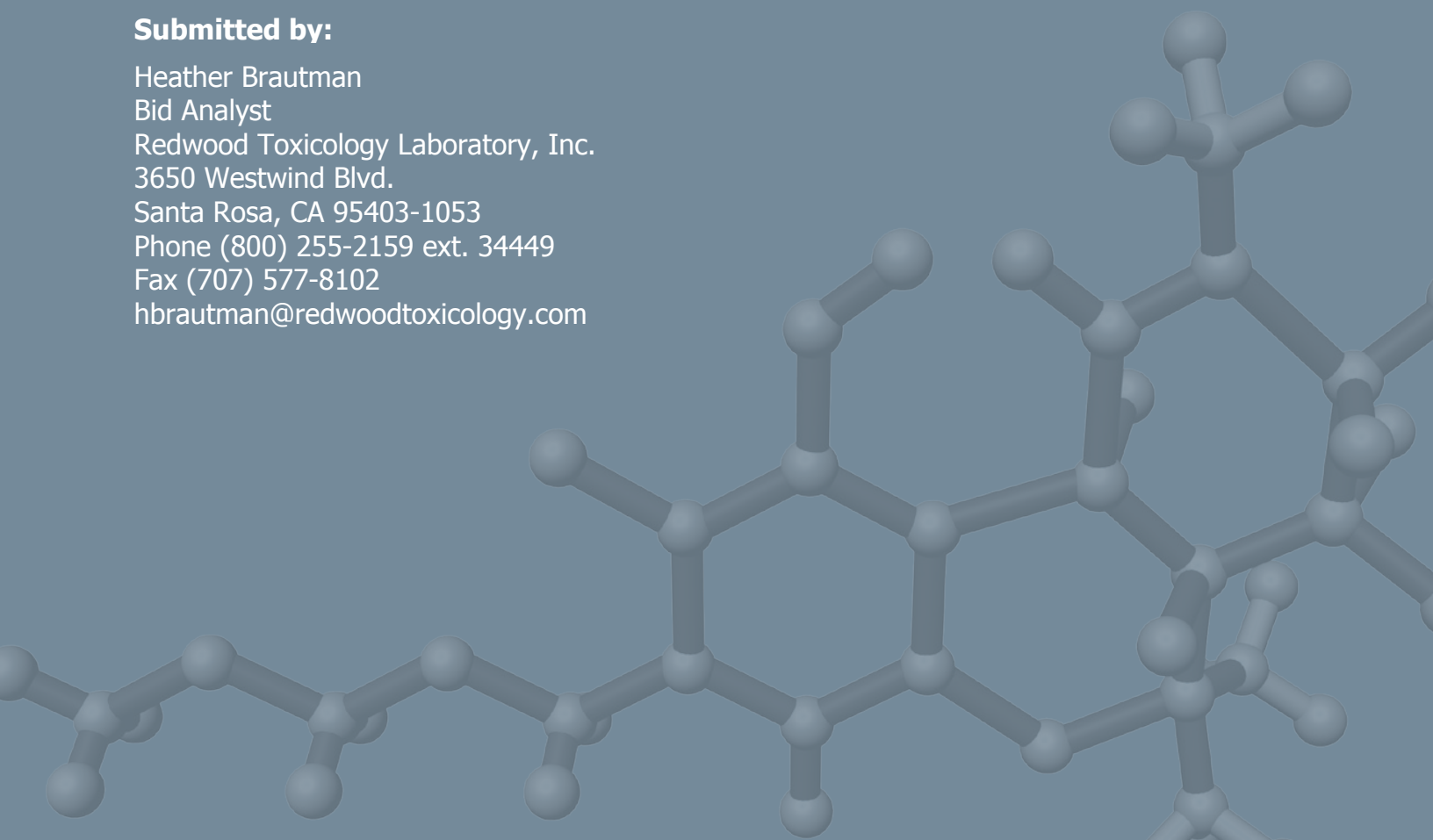
State of West Virginia
Purchasing Division

RFQ No. DJS1700000009 - Drug Testing Kits and Supplies
Due Date: April 11, 2017, 1:30 p.m.

TECHNICAL PROPOSAL

Submitted by:

Heather Brautman
Bid Analyst
Redwood Toxicology Laboratory, Inc.
3650 Westwind Blvd.
Santa Rosa, CA 95403-1053
Phone (800) 255-2159 ext. 34449
Fax (707) 577-8102
hbrautman@redwoodtoxicology.com



3650 Westwind Boulevard
Santa Rosa, CA 95492
phone 800.255.2159
fax 707.577.8102

April 10, 2017

State of West Virginia Purchasing Division
Department of Administration, Bid Clerk
Ms. Crystal Rink
2019 Washington St. E
Charleston, WV 25305

Re: ***DJS1700000009 – Drug Testing Kits and Supplies***

Dear Ms. Rink:

Redwood Toxicology Laboratory, Inc. (RTL) is pleased to present this response to RFQ DJS1700000009 for Drug Testing Kits and Supplies for the State of West Virginia. RTL is the largest single-location drug testing laboratory in the United States. We currently process over 100,000 urine and oral fluid specimens at our Santa Rosa, California facility each week, or over five million tests each year. In addition to comprehensive lab services, RTL offers a complete line of rapid test devices. We sell more than 14 million devices each year from our on-location warehouse.

RTL is trusted by more than 15,000 agencies nationwide. We have extensive experience with correctional agencies, probation/parole, community corrections, juvenile facilities, and drug courts across the country. In fact, RTL is the incumbent provider of laboratory services and rapid test devices for the West Virginia Department of Corrections. We hold state-level contracts in over two dozen states for our laboratory drug testing services and rapid drug and alcohol test devices. This vast experience, especially with our focus on correctional agencies, allows RTL to respond to this bid with an excellent understanding of the objectives of the State of West Virginia, as well as the means and resources necessary to achieve your goals.

In addition, RTL is an industry leader in providing testing solutions to combat the country's most troubling drug use trends and will readily adapt to your changing needs. RTL was the first lab in the world to develop urine-based metabolite testing for synthetic cannabinoids. What's more, we continue to add new compounds to our tests and recently lowered our cut-off levels to ensure that newer-generation synthetic products don't slip through the cracks. In an effort to deter abuse and monitor emerging substances, RTL continually analyzes new products and, if selected, will endeavor to help your agency keep pace with new trends. To this end, we have provided the State with a full pricing schedule of our laboratory services and rapid tests to choose from, should we be awarded this contract; please find this menu available in the Cost Proposal portion of our submission.

If chosen, RTL will supply outstanding and cost-effective urinalysis drug testing supplies and services. We are certain that the West Virginia Department of Administration will be impressed with our high quality drug testing services and dedication to customer satisfaction. If you have any questions regarding this proposal response, please do not hesitate to contact me at (800) 255-2159, ext. 34449, or by email at hbrautman@redwoodtoxicology.com.

Sincerely,

Heather Brautman

Bid Analyst

Table of Contents – Technical Proposal

Purchasing Divison
2019 Washington Street East
Post Office Box 50130
Charleston, WV 25305-0130

State of West Virginia
Request for Quotation
23 — Laboratory

Proc Folder: 311309
Doc Description: DRUG TESTING KITS AND SUPPLIES
Proc Type: Central Master Agreement

Date Issued	Solicitation Closes	Solicitation No	Version
2017-03-09	2017-03-28 13:30:00	CRFQ 0621 DJS1700000009	1

BID RECEIVING LOCATION

BID CLERK
DEPARTMENT OF ADMINISTRATION
PURCHASING DIVISION
2019 WASHINGTON ST E
CHARLESTON WV 25305
US

VENDOR

Vendor Name, Address and Telephone Number:

Redwood Toxicology Laboratory
3650 Westwind Boulevard
Santa Rosa, CA 95403

800-255-2159

FOR INFORMATION CONTACT THE BUYER

Crystal Rink
(304) 558-2402
crystal.g.rink@wv.gov

Signature X [signature] FEIN # 68-0332937 DATE 4/10/17

All offers subject to all terms and conditions contained in this solicitation

DESIGNATED CONTACT: Vendor appoints the individual identified in this Section as the Contract Administrator and the initial point of contact for matters relating to this Contract.

(Name, Title)
Staci Hart, Director of Sales

(Printed Name and Title)
3650 Westwind Boulevard, Santa Rosa, CA 95403

(Address)
800-255-2159 x 4394 / 707-577-8102

(Phone Number) / (Fax Number)
shart@redwoodtoxicology.com

(email address)

CERTIFICATION AND SIGNATURE: By signing below, or submitting documentation through wvOASIS, I certify that I have reviewed this Solicitation in its entirety; that I understand the requirements, terms and conditions, and other information contained herein; that this bid, offer or proposal constitutes an offer to the State that cannot be unilaterally withdrawn; that the product or service proposed meets the mandatory requirements contained in the Solicitation for that product or service, unless otherwise stated herein; that the Vendor accepts the terms and conditions contained in the Solicitation, unless otherwise stated herein; that I am submitting this bid, offer or proposal for review and consideration; that I am authorized by the vendor to execute and submit this bid, offer, or proposal, or any documents related thereto on vendor's behalf; that I am authorized to bind the vendor in a contractual relationship; and that to the best of my knowledge, the vendor has properly registered with any State agency that may require registration.

Redwood Toxicology Laboratory

(Company)

(Authorized Signature) (Representative Name, Title)

Barry Chapman, Chief Financial Officer

(Printed Name and Title of Authorized Representative)

4/10/2017

(Date)

800-255-2159 / 707-676-1847

(Phone Number) (Fax Number)

ADDENDUM ACKNOWLEDGEMENT FORM
SOLICITATION NO.: DJS1700000009

Instructions: Please acknowledge receipt of all addenda issued with this solicitation by completing this addendum acknowledgment form. Check the box next to each addendum received and sign below. Failure to acknowledge addenda may result in bid disqualification.

Acknowledgment: I hereby acknowledge receipt of the following addenda and have made the necessary revisions to my proposal, plans and/or specification, etc.

Addendum Numbers Received:
(Check the box next to each addendum received)

[✓] Addendum No. 1	[ ] Addendum No. 6
[✓] Addendum No. 2	[ ] Addendum No. 7
[✓] Addendum No. 3	[ ] Addendum No. 8
[ ] Addendum No. 4	[ ] Addendum No. 9
[ ] Addendum No. 5	[ ] Addendum No. 10

I understand that failure to confirm the receipt of addenda may be cause for rejection of this bid. I further understand that any verbal representation made or assumed to be made during any oral discussion held between Vendor's representatives and any state personnel is not binding. Only the information issued in writing and added to the specifications by an official addendum is binding.

Redwood Toxicology Laboratory
Company

Authorized Signature

4/10/17
Date

NOTE: This addendum acknowledgement should be submitted with the bid to expedite document processing.
Revised 6/8/2012

11.2 The following remedies shall be available to Agency upon default.

11.2.1 Immediate cancellation of the Contract.

11.2.2 Immediate cancellation of one or more release orders issued under this Contract.

11.2.3 Any other remedies available in law or equity.

12. MISCELLANEOUS:

12.1 **No Substitutions:** Vendor shall supply only Contract Items submitted in response to the Solicitation unless a contract modification is approved in accordance with the provisions contained in this Contract.

12.2 **Vendor Supply:** Vendor must carry sufficient inventory of the Contract Items being offered to fulfill its obligations under this Contract. By signing its bid, Vendor certifies that it can supply the Contract Items contained in its bid response.

12.3 **Reports:** Vendor shall provide quarterly reports and annual summaries to the Agency showing the Agency's items purchased, quantities of items purchased, and total dollar value of the items purchased. Vendor shall also provide reports, upon request, showing the items purchased during the term of this Contract, the quantity purchased for each of those items, and the total value of purchases for each of those items. Failure to supply such reports may be grounds for cancellation of this Contract.

12.4 **Contract Manager:** During its performance of this Contract, Vendor must designate and maintain a primary contract manager responsible for overseeing Vendor's responsibilities under this Contract. The Contract manager must be available during normal business hours to address any customer service or other issues related to this Contract. Vendor should list its Contract manager and his or her contact information below.

Contract Manager: Staci Hart
Telephone Number: 800-255-2159 x4394
Fax Number: 707-577-8102
Email Address: shart@redwoodtoxicology.com

Rev. 04/14

State of West Virginia
VENDOR PREFERENCE CERTIFICATE

Certification and application* is hereby made for Preference in accordance with ***West Virginia Code***, §5A-3-37. (Does not apply to construction contracts). ***West Virginia Code***, §5A-3-37, provides an opportunity for qualifying vendors to request (at the time of bid) preference for their residency status. Such preference is an evaluation method only and will be applied only to the cost bid in accordance with the ***West Virginia Code***. This certificate for application is to be used to request such preference. The Purchasing Division will make the determination of the Vendor Preference, if applicable.

1. **Application is made for 2.5% vendor preference for the reason checked:**

N/A Bidder is an individual resident vendor and has resided continuously in West Virginia for four (4) years immediately preceding the date of this certification; **or,**

N/A Bidder is a partnership, association or corporation resident vendor and has maintained its headquarters or principal place of business continuously in West Virginia for four (4) years immediately preceding the date of this certification; or 80% of the ownership interest of Bidder is held by another individual, partnership, association or corporation resident vendor who has maintained its headquarters or principal place of business continuously in West Virginia for four (4) years immediately preceding the date of this certification; **or,**

N/A Bidder is a nonresident vendor which has an affiliate or subsidiary which employs a minimum of one hundred state residents and which has maintained its headquarters or principal place of business within West Virginia continuously for the four (4) years immediately preceding the date of this certification; **or,**

2. **Application is made for 2.5% vendor preference for the reason checked:**

N/A Bidder is a resident vendor who certifies that, during the life of the contract, on average at least 75% of the employees working on the project being bid are residents of West Virginia who have resided in the state continuously for the two years immediately preceding submission of this bid; **or,**

3. **Application is made for 2.5% vendor preference for the reason checked:**

N/A Bidder is a nonresident vendor employing a minimum of one hundred state residents or is a nonresident vendor with an affiliate or subsidiary which maintains its headquarters or principal place of business within West Virginia employing a minimum of one hundred state residents who certifies that, during the life of the contract, on average at least 75% of the employees or Bidder's affiliate's or subsidiary's employees are residents of West Virginia who have resided in the state continuously for the two years immediately preceding submission of this bid; **or,**

4. **Application is made for 5% vendor preference for the reason checked:**

N/A Bidder meets either the requirement of both subdivisions (1) and (2) or subdivision (1) and (3) as stated above; **or,**

5. **Application is made for 3.5% vendor preference who is a veteran for the reason checked:**

N/A Bidder is an individual resident vendor who is a veteran of the United States armed forces, the reserves or the National Guard and has resided in West Virginia continuously for the four years immediately preceding the date on which the bid is submitted; **or,**

6. **Application is made for 3.5% vendor preference who is a veteran for the reason checked:**

N/A Bidder is a resident vendor who is a veteran of the United States armed forces, the reserves or the National Guard, if, for purposes of producing or distributing the commodities or completing the project which is the subject of the vendor's bid and continuously over the entire term of the project, on average at least seventy-five percent of the vendor's employees are residents of West Virginia who have resided in the state continuously for the two immediately preceding years.

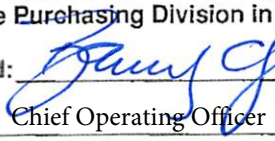
7. **Application is made for preference as a non-resident small, women- and minority-owned business, in accordance with *West Virginia Code* §5A-3-59 and *West Virginia Code of State Rules*.**

N/A Bidder has been or expects to be approved prior to contract award by the Purchasing Division as a certified small, women- and minority-owned business.

Bidder understands if the Secretary of Revenue determines that a Bidder receiving preference has failed to continue to meet the requirements for such preference, the Secretary may order the Director of Purchasing to: (a) reject the bid; or (b) assess a penalty against such Bidder in an amount not to exceed 5% of the bid amount and that such penalty will be paid to the contracting agency or deducted from any unpaid balance on the contract or purchase order.

By submission of this certificate, Bidder agrees to disclose any reasonably requested information to the Purchasing Division and authorizes the Department of Revenue to disclose to the Director of Purchasing appropriate information verifying that Bidder has paid the required business taxes, provided that such information does not contain the amounts of taxes paid nor any other information deemed by the Tax Commissioner to be confidential.

Under penalty of law for false swearing (West Virginia Code, §61-5-3), Bidder hereby certifies that this certificate is true and accurate in all respects; and that if a contract is issued to Bidder and if anything contained within this certificate changes during the term of the contract, Bidder will notify the Purchasing Division in writing immediately.

Bidder: Redwood Toxicology Laboratory, Barry Chapman **Signed:** 

Date: 4/10/17 **Title:** Chief Operating Officer

RFQ No. DJS1700000009

STATE OF WEST VIRGINIA
Purchasing Division

PURCHASING AFFIDAVIT

MANDATE: Under W. Va. Code §5A-3-10a, no contract or renewal of any contract may be awarded by the state or any of its political subdivisions to any vendor or prospective vendor when the vendor or prospective vendor or a related party to the vendor or prospective vendor is a debtor and: (1) the debt owed is an amount greater than one thousand dollars in the aggregate; or (2) the debtor is in employer default.

EXCEPTION: The prohibition listed above does not apply where a vendor has contested any tax administered pursuant to chapter eleven of the W. Va. Code, workers' compensation premium, permit fee or environmental fee or assessment and the matter has not become final or where the vendor has entered into a payment plan or agreement and the vendor is not in default of any of the provisions of such plan or agreement.

DEFINITIONS:

"Debt" means any assessment, premium, penalty, fine, tax or other amount of money owed to the state or any of its political subdivisions because of a judgment, fine, permit violation, license assessment, defaulted workers' compensation premium, penalty or other assessment presently delinquent or due and required to be paid to the state or any of its political subdivisions, including any interest or additional penalties accrued thereon.

"Employer default" means having an outstanding balance or liability to the old fund or to the uninsured employers' fund or being in policy default, as defined in W. Va. Code § 23-2c-2, failure to maintain mandatory workers' compensation coverage, or failure to fully meet its obligations as a workers' compensation self-insured employer. An employer is not in employer default if it has entered into a repayment agreement with the Insurance Commissioner and remains in compliance with the obligations under the repayment agreement.

"Related party" means a party, whether an individual, corporation, partnership, association, limited liability company or any other form or business association or other entity whatsoever, related to any vendor by blood, marriage, ownership or contract through which the party has a relationship of ownership or other interest with the vendor so that the party will actually or by effect receive or control a portion of the benefit, profit or other consideration from performance of a vendor contract with the party receiving an amount that meets or exceed five percent of the total contract amount.

AFFIRMATION: By signing this form, the vendor's authorized signer affirms and acknowledges under penalty of law for false swearing (*W. Va. Code* §61-5-3) that neither vendor nor any related party owe a debt as defined above and that neither vendor nor any related party are in employer default as defined above, unless the debt or employer default is permitted under the exception above.

WITNESS THE FOLLOWING SIGNATURE:

Vendor's Name: Redwood Toxicology Laboratory

Authorized Signature: _____ Date: 4-10-17

State of California

County of Sonoma, to-wit:

Taken, subscribed, and sworn to before me this 10 day of April, 2017.

My Commission expires _____, 20___.

See attached certificate

AFFIX SEAL HERE NOTARY PUBLIC _____

CALIFORNIA JURAT WITH AFFIANT STATEMENT **GOVERNMENT CODE § 8202**

☒ See Attached Document (Notary to cross out lines 1–6 below)
☐ See Statement Below (Lines 1–6 to be completed only by document signer[s], *not* Notary)

1 ———————
2 ———————
3 ———————
4 ———————
5 ———————
6 ———————

Signature of Document Signer No. 1 *Signature of Document Signer No. 2 (if any)*

A notary public or other officer completing this certificate verifies only the identity of the individual who signed the document to which this certificate is attached, and not the truthfulness, accuracy, or validity of that document.

State of California
County of Sonoma

Subscribed and sworn to (or affirmed) before me on this 10th day of April, 2017,
Date *Month* *Year*
by
(1) Barry Chapman
(and (2) ———————),
Name(s) of Signer(s)

proved to me on the basis of satisfactory evidence to be the person(s) who appeared before me.

GINA MAZZOCCO
Commission # 2108841
Notary Public - California
Sonoma County
My Comm. Expires Apr 26, 2019

Signature G. Mazzocco
Signature of Notary Public

Seal
Place Notary Seal Above

OPTIONAL

Though this section is optional, completing this information can deter alteration of the document or fraudulent reattachment of this form to an unintended document.

Description of Attached Document

Title or Type of Document: Purchasing Affidavit - WV Document Date: 4/10/17

Number of Pages: 1 Signer(s) Other Than Named Above: None

3650 Westwind Boulevard
Santa Rosa, CA 95492
phone 800.255.2159
fax 707.577.8102

Response to Technical Specifications

Below are Redwood Toxicology Laboratory's (RTL) responses to the specifications from the bid solicitation. The items in **black** are the taken directly from the bid document(s) and RTL's responses are in **green**.

---

3. QUALIFICATIONS: Vendor shall have the following minimum qualifications.

3.1 For laboratory confirmation services, a minimum of five (5) years' experience, to include state and/or detention and youth reporting centers with a proven ability to process a high quantity of drug screens.

Redwood Toxicology Laboratory, Inc. (RTL), a subsidiary of Alere, Inc., is a federally certified laboratory specializing in accurate and rapid turnaround drug testing in both urine and oral fluids. RTL has provided laboratory-based drugs of abuse testing since its inception in 1994 and drugs of abuse screening devices since 1998. With our considerable experience performing forensic toxicology analyses and selling rapid test devices, our highly qualified staff, state of the art scientific instrumentation, excellent client services, and extensive quality assurance/quality control procedures, RTL has the means to supply the West Virginia Division of Juvenile Services (DJS) and Department of Corrections (DOC) with the highest quality drug testing products and services.

We think our numbers speak strongly to the quality of our products and services, as well as to the satisfaction of our customers. RTL is the largest single-location drug testing laboratory in the United States, processing over 100,000 urine and oral fluid specimens at our Santa Rosa, California facility each week, or over 5 million tests each year. In addition to our comprehensive lab services, RTL offers a complete line of rapid test devices. We sell more than 14 million of our rapid test devices each year from our on-location warehouse. All told, RTL currently provides drug testing services to more than 15,000 agencies across the United States, including departments of corrections, mental and behavioral health departments, children and family services agencies, rehabilitation facilities, probation/parole agencies and drug courts. Holding state-level contracts in over two dozen states for our drug testing products and laboratory services, RTL has the experience, the track record, the capacity, and the drive to make your drug testing program a success.

3.2 For laboratory confirmation services, Vendor shall provide a minimum of three (3) professional references which should include at least one state or county correctional facility. Vendor references should be submitted with bid.

Please see the attached references.

3.3 For laboratory services, Vendor should provide curriculum vitae of Laboratory Director with bid. Documentation must be received prior to award.

Please find curriculum vitaes for Wayne Ross and Dr. Suman Rana included with our response. Brief summaries of their experience appear below.

3650 Westwind Boulevard
Santa Rosa, CA 95492
phone 800.255.2159
fax 707.577.8102

Wayne Ross, M.C.L. S., C.L.S, the chief toxicologist, was awarded a Master's Degree in Clinical Chemistry and Analytical Toxicology from the University of California at San Francisco. He has over 25 years of experience in toxicology and the clinical laboratory. He is a Diplomate of the American Board of Forensic Examiners, a Fellow of the National Academy of Clinical Biochemistry, is licensed by the state of California as a Clinical Laboratory Scientist. He has testified as an expert in forensic toxicology in both state and federal courts in excess of 200 cases. He has worked for RTL since its inception in 1994.

Suman Rana, M.S., Ph.D, the Lab Operations Director at RTL, received her bachelor's degree from Punjab University, Chandigarh, India; her master's degree in Forensic Science (Toxicology) at Punjabi University of Patiala, India; and her Ph.D. in Forensic Science from Bundelkhand University in Jhansi, India. She has over 15 years of management experience in the toxicology field. Suman has overseen the research and development of a number of assays at RTL in the last few years, including our current urinalysis tests for synthetic cannabinoids (K2/Spice) and designer stimulants (Bath Salts) and our oral fluids tests for alcohol, oxycodone, and buprenorphine.

3.4 For laboratory services, Vendor shall be certified by the Substance Abuse & Mental Health Services Administration (SAMSHA), Current Controlled Substance Registration Certificate, and Clinical Laboratory Improvement Amendments (CLIA) for drug testing confirmations. Vendor shall provide proof of such certifications upon request by the Agency.

RTL is licensed and accredited by the following relevant federal and state agencies:

- Department of Health and Human Services (DHHS), CLIA '88
- Participant of the National Laboratory Certification Program (NLCP), mandated by Substance Abuse and Mental Health Services Administration (SAMHSA), Department of Health and Human Services (DHHS)
- California Department of Public Health Clinical Laboratory License #05D0707588
- Drug Enforcement Agency (DEA)

RTL is certified by the Department of Health and Human Services, CLIA '88 and follows their guidelines and requirements to maintain certification.

In Addendum 2, Q&A #55 and #57, the State has indicated that SAMHSA certification is not necessary for the purposes of this bid. As such, RTL intends to process all laboratory specimens through our CLIA laboratory to ensure the most efficient, timely, and cost effective testing for the State. Please note that, if we are awarded, this means the State agrees that any employee tests requested will be processed through the CLIA lab.

3.5 Successful vendor must have their own laboratory and cannot contract out to a third party. Vendor must hold a clinical laboratory license to conduct the testing requested in this solicitation.

RTL has our own laboratory and holds a clinical laboratory license to conduct testing, as requested. RTL will not contract out to a third party for any of the line items included in this bid response.

4. General Requirements

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4.1.1. Customizable All Inclusive On-site Urine Screening Device I Cup Instant Drug Test Kit 13 Panel or Equivalent

For this line item to be "customizable," RTL will be offering a DrugCheck Urine Drug Screen Cup. Please note that there is an FDA-cleared version with FDA-cleared drug strips, or a forensic use only (FUO) version which would allow the State to include drugs such as EtG, Fentanyl, K2/Spice, Ketamine, and Tramadol. Please note that forensic use only (FUO) devices are for use only for law enforcement purposes. These are not designed, tested, developed, or labeled for use in other settings, such as clinical diagnostic or workplace settings. We cannot sell the State any FUO devices for employment testing.

If the State is willing to use RTL's existing cup configuration—the Alere 13-drug iCup (part number 011022028), which includes Amphetamines, Barbiturates, Buprenorphine, Benzodiazepines, Cocaine, Marijuana (THC), Methamphetamine, Methadone, Opiates, Oxycodone, PCP, Propoxyphene, and Tricyclic Antidepressants, but does not have built-in adulteration detection—or the 12-drug iCup A.D. (part number 011022027) which includes the same drugs as the 13-drug iCup, with the exception of missing Buprenorphine—we will offer these products at the reduced costs shown at the bottom of the Pricing Page – Exhibit A.

4.1.1.1 The product shall render accurate results based on historical data and overall averages for the device and drug configuration, within a (5) minute timeframe.

All cups offered in this solicitation will render results in 5 minutes. Accuracy information can be located in the product inserts included with this bid response.

4.1.1.2 The product shall have built in adulteration detection to aid in the prevention of sample tampering.

DrugCheck cup configurations can include 3 measures for adulteration detection.

As stated previously, the 13-drug iCup currently on RTL's catalogue does not come with built-in adulteration detection. However, if the State is willing to consider the 12-drug iCup, we have a configuration (part number 011022027) that includes tests for creatinine, oxidants, and pH.

4.1.1.3 The product shall be all inclusive without a separate testing device.

The cup products offered herein for the 13-drug cup line item are all inclusive without the need for a separate testing device.

4.1.1.4 The product shall have easy to read results. Test result region shall have clear indication of drug indicated test, control line which indicates test is valid, and indication of presence of drug in sample.

The DrugCheck cup and Alere iCup will have easy to read results. All cup devices have an area for the testing region and an area for the control region where a line will indicate that the test has been performed properly.

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4.1.1.5 The product shall be able to detect drugs indicated on the panel simultaneously.

All cups offered in this bid will return results for all included drugs simultaneously.

4.1.1.6 The product shall not leak during air/ground shipping.

The offered cups are designed to prevent leaks, when closed with the lids properly tightened.

4.1.1.7 The cup shall have a minimum fill line clearly displayed on the outside of the cup.

In Addendum 2 Q&A #27, the State indicated that a minimum fill line is no longer required.

4.1.1.8 The Agency reserves the right to change the composition of drugs on the screens at no additional cost. Request for composition of drugs will be indicated at time of order.

The State may change the composition of the DrugCheck test cups at no additional cost. However, please be advised that this will require a minimum order of 500 units and a lead time of at least 2 weeks.

If the State wishes to change to an existing iCup or E-Z Split Key Cup II configuration already offered on RTL's catalogue, this will not require a minimum order or lead time; existing products will be shipped same-day if orders are placed before 2:00 p.m. Pacific Time.

4.1.1.9 The Product shall have a minimum 12 month shelf-life.

All products will be provided with a minimum 12-month shelf life.

4.1.1.10 The product shall include Clinical Laboratory Improvement Amendments (CLIA) cut off levels, and shall have the ability to be confirmed via laboratory confirmation testing.

There are no official CLIA cutoff levels. All products offered will have industry standard cutoff levels, and shall be able to be confirmed via laboratory confirmation testing at RTL's laboratory.

4.1.1.11 Vendor shall provide, at their expense, the following samples upon request:

A. Shipping Bag
B. Shipping container that will hold a minimum of two (2) specimen cup
C. Chain of custody form

RTL provides all necessary urine specimen collection and shipping supplies to our clients at no additional cost. These supplies include:

- Urine specimen collection containers: 60mL or 90mL bottles with lids and built-in temperature strips
- Specimen baggies with absorbent material
- Preprinted Chain of Custody forms/labels and security seals
- Pre-paid FedEx or UPS lab packs or pre-paid U.S. mailer boxes

3650 Westwind Boulevard
Santa Rosa, CA 95492
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If the State wishes to see samples of our shipping packs and chain of custody/test requisition forms, we will send these upon request.

4.1.1.12 Each sterile cup shall be provided in a sealed bag with lot number, expiration date, and drug cut-off levels.

Cup devices offered for this item will be in sealed foil bags with the lot number, expiration date, and configuration printed on the outside.

4.1.2 Panel Saliva Test for oral fluids 6 panel

As part of Addendum 2, the State added a second oral fluids test line item for the DOC. For this line item to be "customizable," RTL will be offering a DrugCheck Saliva Scan oral fluid device.

However, if the State is willing to use RTL's existing cup configuration—the 6-drug iScreen OFD (part number 011022025), which includes Amphetamines, Cocaine, Marijuana (THC), Methamphetamine, Opiates, and PCP—or the OrAlert OFD (part number 011022083)—which includes Amphetamines, Benzodiazepines, Cocaine, Marijuana (THC), Methamphetamine, Opiates, and PCP—we will offer these products at the reduced costs shown at the bottom of the Pricing Page - Exhibit A.

Please note that all oral fluid rapid test devices on the market—with the exception of the Oratect device, which we have also offered at the bottom of Pricing Page - Exhibit A —are labeled for forensic use only (FUO) and will not be able to be utilized for employment screening purposes.

4.1.2.1 The product shall be a 6 panel test including AMP, BAR, COC, MAMP, OPI, and THC.

As described above, RTL can offer a DrugCheck Saliva Scan to meet this configuration exactly. However, if the State is willing to consider alternate configurations, we can offer the iScreen OFD or the OrAlert OFD at reduced costs.

4.1.2.2 Product shall be non-invasive, gender neutral collections with no exposure to specimen.

All oral fluid devices offered will be non-invasive and will allow for gender neutral collections with no exposure to the specimen.

4.1.2.3 The product shall render accurate results based historical data and overall averages for this device and drug configuration within a five (5) minute timeframe.

Per Addendum #2, Q&A #19, the State has indicated that they will allow a result turn-around time of longer than 5 minutes.

The DrugCheck Saliva Scan will render accurate results at 10 minutes (although negative results may be read as soon as two lines appear).

The iScreen® OFD Drug Test Device will render accurate results after 10 minutes.

3650 Westwind Boulevard
Santa Rosa, CA 95492
phone 800.255.2159
fax 707.577.8102

The Oralert® Oral Fluid Drug Screen Device will render accurate results after 9 minutes.

The Alere Oratect® Oral Fluid Drug Screen Device will render accurate results after 5 minutes.

4.1.2.4 The product shall be a packaged all-inclusive unit without a separate testing device, with the ability to detect multiple drugs.

No additional/separate instrumentation is necessary to use with any of the oral fluid test devices offered.

4.1.2.5 The product shall have easy to read results. Test result region shall have clear indication of drug indicated test, control line which indicates test is valid, and indication of presence of drug in sample.

All oral fluid test devices offered have easy to read results with a test result region and a control region.

4.1.2.6 The product shall be able to detect drugs indicated on the panel simultaneously.

All oral fluid test devices offered shall be able to detect drugs indicated on the panel simultaneously.

4.1.2.7 The Product shall have a minimum 12-month shelf life.

All oral fluid test device products will be provided with a minimum 12-month shelf life.

4.1.2.8 The product shall include Clinical Laboratory Improvement Amendments (CLIA) cut off levels, and shall have the ability to be confirmed via laboratory confirmation testing.

There are no official CLIA cutoff levels. All products offered will have industry standard cutoff levels, and shall be able to be confirmed via laboratory confirmation testing at RTL's laboratory.

4.1.2.9 Vendor shall provide, at their expense, the following samples upon request:

A. Shipping Bag
B. Shipping container that will hold a minimum of two (2) specimen cups
C. Chain of custody form

As indicated previously, if the State wishes to see samples of our shipping packs and chain of custody/test requisition forms, we will send these upon request.

4.1.2.10 Each test shall be provided in a sealed bag with lot number, expiration date, and drug cut-off levels.

Each oral fluid device is packaged in a sealed bag containing the part number, lot number, expiration date, and configuration for all included drugs.

3650 Westwind Boulevard
Santa Rosa, CA 95492
phone 800.255.2159
fax 707.577.8102

4.1.2.11 The product shall have fast turn-around time from receipt of specimen (48 hours for negative, 72 hours for positive).

Below are the standard turn-around times for RTL to return results once we receive specimens at the laboratory.

For **standard urine panels**, negative results are reported within twenty-four (24) hours after receipt of the specimen in the laboratory. For confirmation of positives by GC-MS, LC-MS/MS or GC-FID, an additional forty-eight (48) to seventy-two (72) hours may be necessary. Please note that this turnaround time excludes weekends and federal holidays. Additional time may also be required if retesting is necessary for validation.

For **standard oral fluids panels**, negative results are reported within twenty-four (24) to forty-eight (48) hours after receipt of the specimen in the laboratory. Confirmation of positives by GC-MS or LC-MS/MS will be provided within seventy-two (72) to ninety-six (96) hours of receipt of specimen. Please note that this turnaround time excludes weekends and federal holidays. Additional time may also be required if retesting is necessary for validation.

For **specialty urine tests** such as Synthetic Cannabinoids (K2/Spice) or Designer Stimulants (Bath Salts), results will be reported within seventy-two (72) to ninety-six (96) hours after receipt of the specimen in the laboratory. Please note that this turnaround time excludes weekends and federal holidays. Additional time may also be required if retesting is necessary for validation.

4.1.2.12 Each oral swab kit shall be provided in a sealed bag with lot number, expiration date, and drug cut-off levels.

Each device is packaged in a sealed bag containing the part number, lot number, expiration date, and configuration for all included drugs.

4.1.3 ALL Inclusive On-Site Urine Screening Device-- I Cup Instant Drug Test Kit 8 panel or equivalent

4.1.3.1 The Product shall be an 8 panel test including COC, AMP, MAMP, THC, OPI, PCP, BAR, and BZO.

RTL will offer the State the following 8-panel Alere iCup A.D. to meet the requested drug configuration:

- iCup A.D. part number 011022038 - AMP1000, BAR, BZO, COC300, MAMP1000, OPI2000, PCP, THC, with adulteration

For the customizable option for the DOC, RTL would offer the DrugCheck cup device. However, if the DOC also wishes to use the iCup A.D., we will offer them this cup (part number 011022038) at the same price as we are offering to the DJS.

4.1.3.2 The agency will need the ability to test separately for Nicotine (NIC) only and will be listed as separate line item.

3650 Westwind Boulevard
Santa Rosa, CA 95492
phone 800.255.2159
fax 707.577.8102

RTL offers a single cassette device test kit for urine cotinine (nicotine metabolite), part number 011020140 or a single DrugCheck panel dip device. We will offer either device with a free specimen collection bottle, if needed. If the State wishes to use the dip or cassette in tandem with the iCup or DrugCheck cup, they may use the iCup or DrugCheck device as the collection cup.

4.1.3.3 The agency will need the ability to test separately for Buprenorphine (BUP) only and will be listed as separate line item.

RTL offers a single panel dip for Buprenorphine, part number 011020173.

4.1.3.4 The product shall render accurate results based on historical data and overall averages for the device and drug configuration, within a five (5) minute timeframe.

The cups and Cotinine and Buprenorphine devices described above will all render accurate results within 5 minutes.

4.1.3.5 The product shall have built in adulteration detection to aid in the prevention of sample tampering.

The 8-drug iCup AD part number 011022038 has built-in adulteration, including oxidants, specific gravity, and pH. The DrugCheck device can also be customized to include 3 adulterants.

4.1.3.6 The product shall be all inclusive without a separate testing device.

The iCup and DrugCheck cup are all-inclusive without a separate testing device. The Buprenorphine or Cotinine dip devices will need a specimen collection receptacle, but we will provide a collection bottle free of charge with the purchase of each device, if the State will not be using these in tandem with the test cups.

4.1.3.7 The product shall have easy to read results. Test result region shall have clear indication of drug indicated test, control line which indicates test is valid, and indication of presence of drug in sample.

The iCup, DrugCheck cup, Buprenorphine dip, Cotinine cassette or dip all have easy to read results. All devices have an area for the testing region and an area for the control region where a line will indicate that the test has been performed properly.

4.1.3.8 The product shall be able to detect drugs indicated on the panel simultaneously.

The iCup and DrugCheck cup will be able to detect drugs indicated on the test panel simultaneously.

4.1.3.9 The product shall not leak during air/ground shipping.

3650 Westwind Boulevard
Santa Rosa, CA 95492
phone 800.255.2159
fax 707.577.8102

The iCup A.D. is designed to collect specimen and to be shipped back to the laboratory for testing. It should not leak during shipping as long as the lid is properly fastened. The DrugCheck cup should also not leak and be safe for transporting specimens back to the laboratory. The specimen collection bottles for the Buprenorphine or Cotinine dip are also safe for shipping back to the laboratory for testing, as long as the caps are properly screwed on.

4.1.3.10 The cup shall have a minimum fill line clearly displayed on the outside of the cup.

In Addendum 2 Q&A #27, the State indicated that a minimum fill line is no longer required.

4.1.3.11 The Product shall have a minimum 12 month shelf life.

RTL will provide all products with a minimum 12-month shelf life.

4.1.3.12 The product shall include Clinical Laboratory Improvement Amendments (CLIA) cut off levels, and shall have the ability to be confirmed via laboratory confirmation testing.

As described previously, there are no official CLIA cutoff levels. All products offered will have industry standard cutoff levels, and shall be able to be confirmed via laboratory confirmation testing at RTL's laboratory.

4.1.3.13 Vendor shall provide, at their expense, the following samples upon request:
A. Shipping Bag
B. Shipping container that will hold a minimum of two (2) specimen cups
C. Chain of custody form

As indicated previously, if the State wishes to see samples of our shipping packs and chain of custody/test requisition forms, we will send these upon request.

4.1.3.14 Each sterile cup shall be provided in a sealed bag with lot number, expiration date, and drug cut-off levels.

Each device is packaged in a sealed bag containing the part number, lot number, expiration date, and configuration for all included drugs.

4.1.4 Training

4.1.4.1 Vendor shall provide initial in-person training course(s) at no additional cost to the Agency to ensure that the Agency performs effective drug screens in a manner consistent with manufacturer recommendations. In addition, vendor will provide in-depth and interactive training procedures for additional staff training. Vendor will provide additional training should any change in product warrant such supplemental training. Vendor will provide a certification process in which, train the trainers are able to certify other users and provide a "certificate" upon successful completion of the competency.

3650 Westwind Boulevard
Santa Rosa, CA 95492
phone 800.255.2159
fax 707.577.8102

RTL offers a variety of useful training resources to our clients—trainings may be provided via online training modules, webinar training, or on-location training. These will all be provided as needed and at no additional cost to the State. We encourage your agency to utilize online and webinar-based options, as they allow more flexibility for your staff.

For agencies interested in web-based training, RTL is able to offer Learning XChange, a complete system designed for on-demand training. The in-depth training procedures available through this online system will ensure that members of an organization are trained to perform drug screens in a manner consistent with manufacturer recommendations. Each user will create his or her own account following initial login to the agency's Learning XChange "group" page. When a course is completed, users may test their knowledge by successfully completing a quiz. If the quiz is passed, the user will receive a Certificate of Completion to print or save as a PDF document. Each user's information (name, phone number, email address) will remain associated with his or her specific group (agency) so each user may track which courses he or she has completed.

RTL has also made informational brochures available online for reference. Our website includes information materials about site preparation; urine collection; specimen verification; problematic collections; specimen disposal; and proper labeling, packaging and shipping procedures. You can find these materials at https://www.redwoodtoxicology.com/resources/collection and in our Reference Guide, which is available to clients at no charge. Please note that our specimen collection materials are guidelines only; it is the responsibility of the individual agency to adopt their own policies and procedures according to their needs in compliance with their State and Federal regulations.

4.1.5 Additional Testing Kit Requirements

4.1.5.1 The kits shall have a built-in specimen validity testing for three or more of the following: Oxidants, Specific Gravity, pH, Nitrite, Glutaraldehyde, and Creatinine.

The DrugCheck cups may be requested with adulteration for three specimen validity checks, including your choice of Creatinine, Nitrite, pH, Oxidants, or Specific Gravity. iCups from our existing catalogue will indicate which adulterants—if any—are included in the configuration.

4.1.5.2 Urinalysis screening drug testing kit shall be convenient and ready to use at any location.

The rapid test devices offered herein are portable, safe, and ready to use at any location. Each kit comes in its own protective foil bag with the expiration date printed on the outside. Specimen collectors can quickly and easily grab the needed quantity and begin testing at any location.

4.1.5.3 Drug testing kits shall not require any mixing of reagents or pretreatments/special handling of urine samples.

3650 Westwind Boulevard
Santa Rosa, CA 95492
phone 800.255.2159
fax 707.577.8102

Fresh urine requires no special handling or pretreatment. However, RTL has gloves available for purchase, should the State desire this extra measure of protection from exposure to urine or saliva.

4.1.5.4 Drug testing kits shall be capable of producing results within five (5) minutes and results shall be stable for a minimum of one hour.

In Addendum #2, Q&A #19, the State indicated that they would consider longer turnaround times for results. In Addendum #2, Q&A #21, the State indicated that they would have some flexibility regarding shorter stability windows for results.

All iCups and the Buprenorphine dip will produce results within 5 minutes and results will be stable for a minimum of one hour.

DrugCheck cups will produce results within 5 minutes and results should be read within 10 minutes.

SalivaScan oral fluid devices will produce results within 10 minutes and should be read within 20 minutes.

The iScreen OFD will produce results within 10 minutes and results will be stable for up to one hour.

The OrAlert oral fluid device results should be read at 9 minutes.

The Oratect oral fluid device results will be ready within 5 minutes and results should be read within 15 minutes.

Please see the “Offered Devices Comparison” we have included with our Cost Proposal to help the State more easily compare the differences between devices.

4.1.5.5 Vendor shall provide kits that are easy to determine the result clearly and concisely.

The drugs of abuse screening devices offered by RTL are easy to read to aid in correct interpretation of results. If two lines appear on the device after administering the test, one in the control region (C), and one in the test region (T), the specimen is negative. The testing region must be snow-white to be considered positive. To ensure quality, a control line is included on each screening device. Each package insert includes instructions for use.

4.1.5.6 Drug testing kit shall not require refrigeration.

Test kits do not require refrigeration. Store the quoted devices packaged in their sealed pouches at 2-30°C (36-86°F). Do not use beyond the expiration date printed on the front of each individual drug test kit.

4.1.5. 7 Drug testing kit shall have a built-in temperature strip to indicate validity of specimen.

3650 Westwind Boulevard
Santa Rosa, CA 95492
phone 800.255.2159
fax 707.577.8102

All cup devices offered will have a built-in temperature strip. Bottles offered for use with panel-dip devices will also include temperature strips.

Oral fluid devices offered will not include temperature strips, as oral fluid specimens are easier to observe and harder to adulterate.

4.1.5.8 Vendor shall provide a drug testing kit wherein the screening results can be photocopied as a permanent record.

In Addendum #2, Q&A #68, the State indicated that round cups would be acceptable. iCups, panel-dips, and certain DrugCheck cups (FUO only) have flat panel test areas that may be photocopied. Other DrugCheck cups (FDA-cleared) and some OFDs are not flat for photocopying, but may be photographed using a digital camera device.

Please note that RTL also offers our proprietary, web-based ToxAccess system, wherein the State would be able to record results from rapid test devices for storage in the system, if desired. Using ToxAccess, the State would also have immediate access to online results for laboratory test results, as well as the ability to email, print, and archive results and pull statistical reports.

4.1.5.9 Drug testing kits shall include a built-in procedural control that confirms sufficient specimen volume, adequate membrane wicking, and correct procedural technique.

Each device has a procedural control included in the test. A line appearing in the Control region is considered an internal procedural control. It confirms sufficient specimen volume, adequate membrane wicking, and correct procedural technique.

4.1.5.10 Vendor shall provide for each single donor cup a preprinted chain of custody with specimen ID not to exceed 15 characters and a self-adhesive peel-off label with matching specimen ID number.

RTL will offer test requisition/chain of custody forms for the State to utilize for sending specimens to our laboratory for testing in either a standard collection bottle or directly in the rapid test cup or oral fluid device. Preprinted forms come with a requisition number shown both on the form and on the self-adhesive peel-off label. The requisition number can include up to 16 characters, although numbers generated by RTL are currently only 6 digits long. The unique ID field on the preprinted form and label for the collector to write onto the form and has a character limit of 20 characters (separate from the donor name fields); the State may use as many (up to 20) or as few as they like to identify the donor using this unique ID field.

RTL also offers a web-based, one-part chain of custody forms through our proprietary website, www.ToxAccess.com. No special hardware or software is required other than a computer with Internet access and a printer. When using the ToxAccess collections features, the need for hand-written chain of custody forms is eliminated. Training on RTL's electronic chain of custody is provided at time of account roll-out and throughout the life of our contract.

3650 Westwind Boulevard
Santa Rosa, CA 95492
phone 800.255.2159
fax 707.577.8102

4.1.5.11 The label shall provide a place to enter collection time, date, and juvenile's initials.

Each test requisition/chain of custody form—preprinted or web-based—will have a peel-off label and a peel-off security seal to place on the device. The label will include a place for the collector name, patient ID, and collection date (web label also includes collection time); the security seal will include a place for the donor's initials. The security seal goes over the cap and the label goes around the bottle—over the security seal—to prevent tampering.

4.1.6 Packaging

4.1.6.1 The Drug Test Kits shall be provided in a sealed bag with lot number, expiration date, drugs cut- off levels.

As stated previously, each device is packaged in a sealed bag containing the part number, lot number, expiration date, and configuration for all included drugs.

4.1.6.2 Vendor shall to supply clear sealable shipping bags and sturdy cardboard shipping containers or lab packs for shipping positive results for lab confirmation.

RTL provides shipping materials compliant with FedEx and UPS shipping requirements for shipping specimens to our laboratory for testing. These will be provided to the State at no charge.

4.1.6.3 The name and location of each Division of Juvenile Services (DJS) Facility as listed in Attachment A. The Vendor shall provide the contract items, at contract price, to any additional DJS facility(s) that may open, or require equipment and supplies during the course of the contract.

RTL is pleased to extend this contract, upon award, to additional DJS and DOC facilities that may require test kits, supplies, and testing.

4.1. 7 Laboratory Confirmation Services

4.1.7.1 Upon award, the successful laboratory confirmation services Vendor shall provide the following ancillary supplies to all Agency facilities listed on Attachment A:

- Specimen collection containers/bottles
- Specimen baggies with absorbent material
- Chain of Custody forms
- Labels of various configurations
- Security Seals
- Pre-paid mailers
- Overnight shipping service lab packs

As described previously, RTL will provide all supplies necessary for collection and shipping specimens to our laboratory for testing. Next day air service of inbound specimens sent to RTL

3650 Westwind Boulevard
Santa Rosa, CA 95492
phone 800.255.2159
fax 707.577.8102

for testing is provided at no charge; however, it is requested that five (5) or more urine and/or oral fluids specimens are sent in each FedEx overnight shipment. Any combination of urine and/or oral fluids devices may be shipped together via FedEx overnight service.

4.1. 7.2 Gas Chromatography/Mass Spectrometry (GC/MS) and/or Liquid Chromatography/Tandem Mass Spectrometry (LC/MS/MS) shall be the testing confirmation method.

RTL uses gas chromatography-mass spectrometry (GC-MS), liquid chromatography-tandem mass spectrometry (LC-MS/MS), or gas chromatography-gas flame ionization (GC-FID)* to perform confirmation testing. Method used depends on drug class.

*GC-FID is only used to confirm ethanol (alcohol).

4.1.7.3 The confirmation laboratory shall be currently certified and maintain certification by the Clinical Laboratory Improvement Amendments (CLIA) for offender confirmations, meet the industry standards for the drug testing programs. A copy of the certification should be provided upon request.

RTL is certified by the Department of Health and Human Services, CLIA '88 and follows their guidelines and requirements to maintain certification. A copy of our certification is available upon request.

4.1.7.4 The confirmation laboratory may, for offender testing, be performed by certified Clinical Laboratory Improvement Amendments (CLIA) licensed laboratories and meet industry standards.

See item 4.1.7.3. above.

4.1.7.5 If the SAMSHA, and/or CLIA certification of the confirmation laboratory is suspended or revoked, Vendor shall notify Agency within ten (10) business days.

RTL strictly adheres to CLIA certification requirements and does not anticipate having its certification suspended or revoked. In such a case, RTL agrees to notify the Agency within 10 business days.

4.1.7.6 Vendor shall provide GC/MS confirmation testing of all positive screens or specimens that Agency requests to be confirmed. The methodology must 1) apply a theory or technique that can be, and has been, tested; 2) the theory or technique must have been subjected to peer review and publication; 3) it must have a known, or potential, error rate; 4) there must be an existence and maintenance of standards controlling its operation.; and 5) it must have attracted widespread acceptance within a relevant scientific community. See Daubert v. Merrell Dow Pharmaceuticals, Inc. 509 US 579 (1993).

In Addendum #2, Q&A #52, the State confirmed that both GC-MS and LC-MS/MS methods would be acceptable. RTL utilizes both GC-MS and LC-MS/MS as confirmation methodologies,

3650 Westwind Boulevard
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depending on drug class. LC-MS/MS is more sensitive and specific than GC-MS, and increases compound identification specificity through the use of two mass spectrometers, versus a single one for GC-MS methods. In Volume 73, No. 228, page 71868 of the Federal Register, the Department of Health & Human Services, Substance Abuse & Mental Health Services Administration (SAMHSA) indicates that LC-MS/MS methodologies have proven to be reliable to test specimens, and produce forensically and scientifically supportable results. Moreover, LC-MS/MS results have proven to be defensible in courts of law across the country. RTL's confirmation cut-off levels meet or exceed (i.e. are more sensitive than) SAMHSA regulation cut-offs.

Juvenile Offenders: The purpose of this testing is for juvenile justice purposes. As such, the Agency requires that the confirmation lab test to limit of detection (LOD), which is consistent with the methodology specified above. The LOD shall reflect the concentrations at which the specific drug can be detected to a reasonable degree of scientific certainty and upon which admissible opinion testimony can be given there from for both facility discipline and juvenile court proceedings.

RTL uses industry standard cutoff levels; as indicated in our answer above, these meet or exceed SAMHSA recommended cutoff levels. RTL's current cutoff levels will be available on our website for your agency to review at any time. The cutoff levels utilized produce scientifically supportable results, and RTL is able to provide expert testimony regarding the methodologies and cutoffs utilized at our laboratory, should the State need this.

4.1.7.7 Ethyl glucuronide (EtG) tests shall be used for alcohol (ethanol) screens. In addition to EtG, Ethyl Sulfate (EtS) shall be used as secondary testing for specific metabolite or biomarker of ethanol. Vendor must test and report EtS, in conjunction with EtG, to confirm recent ethanol ingestion.

Per Addendum #2, Q&A #13, the State confirmed that this line item is for a laboratory test, which is what RTL will be offering for this line item.

Please note that EtG is an alcohol metabolite; screening for EtG is not the same as an ethanol screen (which detects the presence of actual ethanol in the specimen), but it will provide information about the presence of alcohol metabolite in the specimen for up to 80 hours following ingestion of ethanol.

RTL has provided pricing for our EtG laboratory test, including both the screen and confirmation for presumptive positives. EtS is a second specific ethanol biomarker that is produced when ethanol is processed through the liver, and EtS is stable in the presence of bacterial species (unlike ethanol and EtG, which may be produced as the result of fermentation of glucose). Both EtG and EtS will be reported on confirmation results.

4.1. 7.8 The cutoff level for use in the EtG/EtS testing shall be 100 ng/mL. Any EtG level over 100 ng/mL must indicate exposure to ethanol.

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RTL uses a 100 ng/mL cut-off level. An EtG level over 100 ng/mL indicates exposure to ethanol, and the presence of EtS will confirm recent ethanol ingestion or exposure.

4.1.7.9 The successful Vendor for laboratory confirmation services shall provide overnight delivery services to its laboratory for all samples and specimens for both drug and alcohol testing. All alcohol specimens and all positive drug specimens may be shipped to the laboratory for confirmation services.

RTL provides specimen pickup through FedEx or UPS, with overnight service delivery to our laboratory in Santa Rosa, California. RTL will work directly with an Agency representative to determine the best dates and time to pick up specimens from Agency locations.

4.1.7.10 All urine specimens that test positive for drugs, alcohol, and/or metabolites shall be stored at a secure warehouse for a minimum of six (6) months. Negative alcohol specimens will be stored for two (2) days. Additionally, chain of custody records, documentation, and analytical records shall be securely stored for a minimum of three (3) years.

RTL agrees to store positive urine tests for a minimum of 6 months, negative alcohol specimens for 2 days, and chain of custody and other records for 3 years.

4.1. 7.11 Vendor shall provide services of a Medical Review Officer (MRO) on an as needed basis. Said MRO shall review, analyze, and report on confirmed positive test results. When required, MRO shall conduct medical interviews with the donor for any confirmed positive, adulterated, substituted, invalid test results, and if necessary, review donor's medical history. Agency may request expert testimony from MRO in court or grievance proceedings regarding verified positive findings. This must be a per hour bid to include any travel.

It is RTL's policy to not recommend an MRO to an agency, as this is considered a conflict of interest for a laboratory performing testing. Instead we will offer the State analysis and consultation by our toxicologists; these services will be available at no additional charge. RTL will also offer our toxicologists as expert witnesses as needed. Expert witness services are available through written affidavit, telephonically, or in-court. Affidavits and telephonic or web-based testimony will be provided to the State at no charge. Charges for in-person testimony appear on Pricing Page – Exhibit A in the Cost Proposal. When subpoenaed to testify, the toxicologist will produce the chain of custody, laboratory results, quality control data, and GC-MS or LC-MS/MS confirmation of the positive drug(s).

Should the State need to utilize an MRO—such as for an employee test—we are happy to work with an MRO of the State's choosing. We can forward all results or positives only to an MRO at the State's request. The State may find local MROs by going to https://www.aamro.com/find-an-mro.aspx and searching in their state and/or city.

4.1.7.12 Vendor must provide the agency with the most up to date version of each drug testing kit.

RTL will provide the most up to date version of each drug testing kit.

RTL References

Reference #1

Name of Reference Company	West Virginia Supreme Court of Appeals	
Address of Reference Company	Building 1, Room E-100, 1900 Kanawha Boulevard East Charleston, WV 25305	
Reference Contact Person Information	Name:	Michael B. Lacy
	Title:	Director
	Phone:	304-558-0145
	Email Address:	mikelacy@courtswv.gov

Reference #2

Name of Reference Company	Montgomery Counrt Department of Correction & Rehabilitation, Pre-Release Services Division	
Address of Reference Company	11651 Nebel Street Rockville, MD 20852	
Reference Contact Person Information	Name:	Ivan N. Downing, MBA, CSSGB
	Title:	Deputy Chief of Security and Facilities
	Phone:	Office: 240-773-4203; Cell: 240-672-8794
	Email Address:	ivan.downing@montgomerycountymd.gov

Reference #3

Name of Reference Company	39th Judicial Court	
Address of Reference Company	PO Box 18 Galena, MO 65656	
Reference Contact Person Information	Name:	Zach Adams
	Title:	Treatment Court Administrator
	Phone:	417-343-3214
	Email Address:	zach.adams@courts.mo.gov

APPENDIX

Sumandeep Rana, MSc, MBA, PhD.
707 570 4332
srana@redwoodtoxicology.com

PROFESSIONAL SKILLS

- Over 17 years of management experience in the analytical toxicology field, area of interest includes designer drugs and analytical toxicology
- Expert in developing procedures for extraction of drugs of abuse and other medicinally abused drugs from forensic specimens like blood, urine, oral fluids, sweat and hair
- Expert in developing confirmation procedures using Gas Chromatography-Mass Spectrometry (**GC-MS, GC-GC-MS & GC-MS/MS**) and Liquid chromatography-Mass Spectrometry (**LC-MS/MS**) for drugs extracted from blood, urine, oral fluids and hair
- Excellent working experience with new technology like multiplexing and fast chromatography
- Proficient in experiment design for validating new procedures and optimizing existing procedures
- Highly Skilled in planning, organizing, managing, and coordinating the personnel, methods, and procedures for high volume testing laboratories
- Highly skilled in data analysis, report writing, result interpretations and writing Standard Operating Procedures (SOP), policies and documents
- Manage projects independently and responsible for directing day to day functioning of the laboratory including work assignment and technical direction to lab personnel
- Knowledge of SOFT/AAFS/ABFT and SAMHSA laboratory guidelines
- Excellent verbal and written communication and leadership skills including ability to solve complex problems
- Ability to build solid working relationships at all levels via well developed communication skills

PROFESSIONAL AFFILIATIONS

Board Member – SOFT (Society of Forensic Toxicologists). SOFT Treasurer 2017-2018.
Chair – SOFT Designer Drugs Committee Jan 2013 – Feb 2016.
Member – SOFT Designer Drugs Committee
Editorial Board member - Journal of Analytical Toxicology
Member – Toxicology Subcommittee of the Chemistry/Instrumentation Scientific Area Committee (OSAC)
Member - The International Association of Forensic Toxicologists (TIAFT)
Member – Associate Member of American Academy of Forensic Sciences (AAFS)
Member - California Association of Toxicologists (CAT)
Reviewer – Journal of Analytical Toxicology
Reviewer – Journal of Mass Spectrometry
Reviewer – Journal of Forensic Science
Reviewer - Journal of Chromatography

PROFESSIONAL EXPERIENCE

Laboratory Director, Operations and Technology/ HHS Responsible Person: Redwood Toxicology Laboratory, Santa Rosa, CA (Feb 2014-Present)

- Responsible for the overall laboratory operations for three labs at Redwood Toxicology: CLIA Lab, SAMHSA lab and Alere Forensic Lab at Redwood Toxicology.
- Manage and direct the development of the technical SOPs, workflows and personnel of the laboratory to maintain technical/scientific veracity, adherence to prevailing regulatory requirements, and to ensure legal acceptability. Leading a team of over 200 employees.

- Applying scientific principles to qualitatively and quantitatively analyze biological matrices for the presence of controlled substances and/or their metabolites.
- Direct the development and validation of new laboratory procedures and/ or optimize current laboratory procedures or troubleshoot laboratory procedures and / or equipment as necessary.
- Monitoring the preanalytic, analytic, and postanalytic phases of test analyses to ensure that acceptable levels of analytic performance are maintained.
- Perform SAMHSA Responsible Person (RP) duties for the SAMHSA lab as required.
- Make recommendations to the General Manager for the acquisition of lab equipment as needed for improved efficiency or replacement of older equipment.
- Verify that all laboratory results are reported within the laboratory's standard TATs.
- Plan staffing level adequacy in conjunction with the Chief Toxicologist.
- Ensure that employee evaluations are performed as scheduled and all personnel training and competency activities are documented.
- Ensure that all laboratory quality procedures and policies comply with State of Calif., CLIA '88, and all other pertinent regulatory standards (SOFT / AAFS, SAMHSA and CAP-FUDT where applicable), and will participate in laboratory inspections.
- Evaluate and monitor new and current laboratory instrumentation for documentation of performance characteristics and proof of on-going stability.
- Evaluate current methods, equipment and consumables for cost effectiveness.
- Leading the installation, validation, and training for new equipment.
- Provide technical and scientific assistance to laboratory personnel, as well to clients, attorneys, correctional personnel, etc., and with laboratory customer service, sales, and marketing personnel.
- Provide expert court testimony to defend, explain, and interpret laboratory results produced by Redwood Toxicology Laboratory.
- Adhere to all established laboratory standard operating procedures.
- Maintain current level of expertise through continuing education.
- Perform specialized projects as required by General Manager.
- Direct all R&D efforts/projects
- Direct and maintain an on-going training program for lab personnel
- Co-coordinate internal and external proficiency testing activities

Technical Director/ HHS Alt-Responsible Person: Redwood Toxicology Laboratory, Santa Rosa, CA (Feb 2012-Jan 2014)

- Manage and direct the development of the technical SOPs of the laboratory to maintain technical/scientific veracity, adherence to prevailing regulatory requirements, and to ensure legal acceptability.
- Ensure that all laboratory quality procedures and policies comply with State of Calif., CLIA '88, and all other pertinent regulatory standards (SOFT / AAFS, SAMHSA and CAP-FUDT where applicable).
- Applying scientific principles to qualitatively and quantitatively analyze biological matrices for the presence of controlled substances and/or their metabolites.
- Direct the development and validation of new laboratory procedures and/ or optimize current laboratory procedures or troubleshoot laboratory procedures and / or equipment as necessary.
- Monitoring the preanalytic, analytic, and postanalytic phases of test analyses to ensure that acceptable levels of analytic performance are maintained.
- Perform SAMHSA Responsible Person (RP) duties as required.
- Evaluate and monitor new and current laboratory instrumentation for documentation of performance characteristics and proof of on-going stability.
- Evaluate current methods and equipment for cost effectiveness.
- Leading the installation, validation, and training for new equipment.

- Provide technical and scientific assistance to laboratory personnel, as well to clients, attorneys, correctional personnel, etc., and with laboratory customer service, sales, and marketing personnel.
- Provide expert court testimony to defend, explain, and interpret laboratory results produced by Redwood Toxicology Laboratory.
- Direct and maintain a rigorous QC program in the laboratory
- Direct all R&D efforts/projects
- Direct and maintain an on-going training program for lab personnel
- Co-coordinate internal and external proficiency testing activities

Scientific Director: Redwood Toxicology Laboratory, Santa Rosa, CA (Dec 2006-Feb 2012)

- Responsible for applying scientific principles to qualitatively and quantitatively analyze biological matrices for the presence of controlled substances and/or their metabolites
- Responsible for developing and validating new laboratory procedures and/ or optimizing current laboratory procedures and troubleshooting laboratory procedures and/ or equipment as necessary
- Monitoring the preanalytic, analytic and postanalytic phases of test analysis to ensure that acceptable levels of analytic performance are maintained
- Ensuring GC/MS and LC/MS/MS quality control procedures and policies comply with State of California. CLIA' 88 and all other pertinent regulatory standards
- Evaluating and monitoring new and current GC/MS and LC/MS/MS instrumentation for documentation of performance characteristics and proof of on-going stability
- Evaluating current methods and equipment for cost effectiveness
- Leading the installation, validation, and training for new equipment
- Providing scientific and technical assistance/training to clients, laboratory customer service, sales and marketing personnel
- Provide court testimony as expert witness
- Performing specialized research and development projects as required
- Identifying opportunities for new business and developing methods to support that

Research Scientist (Toxicology): Immunalysis Corporation, Pomona, CA, (Jan 2005-Nov 2006)

- Responsible for managing the overall functioning of toxicology research laboratory including writing SOPs, providing technical direction to lab personnel and task assignment
- Responsible for developing extraction and confirmation procedures (**GC-MS**) for drugs of abuse and medical panel drugs from oral fluids, urine, blood and hair
- Designing experiments for validation of the procedures and quality control
- Data analysis and report writing
- Conducting training sessions for customers for oral fluid and hair extraction procedures and GC-MS confirmation methods
- Providing technical support to customers for extraction and analysis methods

Research Chemist: Immunalysis Corporation, Pomona, CA, USA (April 2000-Dec 2004)

- Responsible for development of new immunochemical forensic drug test screens involving isolation of immunoglobulins from antiserum, spectrophotometric quantitation of immunoglobulins following affinity chromatography, biotinylation, purification and immobilization of immunoglobulins on micro titer plates, development of assays (**ELISA and RIA**)
- Evaluation of the assay data using forensic samples
- Comparison of ELISA results with those obtained using gas chromatography-mass spectrometry
- Analysis of compounds of toxicological interest using **TLC, FTIR** and **GC-MS**
- Quality control of existing panel of Forensic Drug Screens involving evaluation of kit performance utilizing multiple forensic specimens based on **FDA** guidelines

Research Fellow (University Grants Commission): Department of Forensic Science, Punjabi University, Patiala, India. (May 1997-August 1999)

- Collection and analysis of data regarding the trend of pesticide poisoning and drug abuse from all over India.
- Detection and analysis of these pesticides and drugs of abuse in biological specimens from forensic point of view using different analytical techniques like **TLC, HPLC, GC-MS, FTIR** and UV-Visible spectroscopy.
- Teaching toxicology and chemistry to graduate classes
- Supervising graduate students in their research projects

EDUCATION

MBA, Executive Program from Sonoma State University, CA
Ph.D., Forensic Science from Bundelkhand University, Jhansi, India
M.S., Forensic Science (Specialization: Toxicology) from Panjabi University, Patiala, India
B.S., Biology/Chemistry from Punjab University, Chandigarh, India
Six-Sigma Yellow Belt Certified Professional.

PUBLICATIONS

Rana S, Garg R K, Singla A. Rapid analysis of urinary opiates using fast gas chromatography-mass spectrometry and hydrogen as a carrier gas. *Egypt J Forensic Sci. 2014*; *http://dx.doi.org/10.1016/j.ejfs.2014.03.001*

Uralets V, **Rana S**, Morgan S, Ross W. Testing for designer stimulants: Metabolic profiles of 16 synthetic cathinones excreted free in human Urine. *J Anal Toxicol* 2014; 38(5): 233-241

Uralets V, App M, **Rana S**, Morgan S, Ross W. Designer phenethylamines routinely found in human urine: 2-ethylamino-1-phenylbutane and 2-amino-1-phenylbutane. *J Anal Toxicol* 2014; 1-4, doi:10.1093/jat/bkt121

Rodrigues C.W, Catbagan P, **Rana S,** Wang G, Moore C. Synthetic cannabinoids in Oral Fluid Using ELISA and LC-MS/MS. *J Anal Toxicol* 2013; 37 (8): 526-533

Thierauf A, Halter C.C, **Rana S**, Auwaerter V, Wohlfarth A, Wurst F.M and Wienmann. Urine tested positive for ethyl glucuronide after trace amounts of ethanol. *Addiction* 2009; 104: 2007-2012

Rana S. Designer drugs proliferate. Addiction Professional 2011; 9(4): 82-83

Thierauf A, Serr A, Halter C.C, Al-Ahmed A, **Rana S** and Wienmann W. Influence of preservatives on the stability of ethyl glucuronide and ethyl sulfate in urine. *Forens Sci Int* 2008; 182(1-3): 41-45

Rana S, Uralets V and Ross W. A new method for simultaneous determination of cyclic antidepressants and their metabolites in urine using enzymatic hydrolysis and fast GC/MS. *J Anal Toxicol* 2008; 32 (5): 355-363.

Moore C, **Rana S**, Coulter C, Day D, Soares J. Detection of conjugated 11-nor-Δ^9-tetra-hydrocannabinol-9-carboxylic acid in oral fluid. *J Anal Toxicol* 2007; 31(5): 187-194

Moore C, **Rana S**, Coulter C. Determination of meperidine, tramadol and oxycodone in human oral fluid using solid phase extraction and gas chromatography-mass spectrometry. *J Chromatogr B Analyt Technol Biomed Life Sci*; 2006; 26(12): 17194631

Rana S, Moore C, Agrawal A, Coulter C, Vincent M, Soares J. Determination of propoxyphene in oral fluid. *J Anal Toxicol* 2006; 30(8): 516-518.

Moore C, Vincent M, **Rana S**, Coulter C, Agrawal A, Soares J. Stability of ∆9-tertahydrocannabinol (THC) in oral fluid using the Quantisal™ collection device. *Forens Sci Int* 2006; 164(2-3): 126-130

Moore C, Ross W, Coulter C, Adams L, **Rana S**, Vincent M, Soares J. Detection of marijuana metabolite, 11-nor-∆9-tetra-hudrocannabinol-9-carboxylic acid (THC-COOH) in oral fluid specimens, and its contribution to positive results in screening assays. *J Anal Toxicol* 2006; 30(7): 413-418

Moore C, Coulter C, **Rana S**, Vincent M, Soares J. Analytical procedure for the determination of the marijuana metabolite, 11-nor-∆9-tetra-hydrocannabinol-9-carboxylic acid (THCA), in oral fluid specimens. *J Anal Toxicol* 2006; 30(7): 409-412

Moore C, Feldman M, Harrison E, **Rana S**, Coulter C, Kuntz D, Agrawal A, Vincent M, Soares J, Disposition of hydrocodone in hair. *J Anal Toxicol* 2006; 30(6): 353-359

Moore C, **Rana S**, Coulter C, Feyerherm F, Prest H. Application of two-dimensional gas chromatography with electron capture chemical ionization mass spectrometry to the detection of 11-nor-∆9-tetra-hydrocannabinol-9-carboxylic acid (THC-COOH) in hair. *J Anal Toxicol* 2006; 30(3): 171-177

Moore C, Feldman M, Giorgi N, Ross W, Harrison E, Irvan D, Kuntz D, Agrawal A, **Rana S**, Vincent M, Soares J. Analysis of amphetamines in hair, oral fluid and urine. *Annales de toxicology Analytique* (SFTA) 2005; XVII no. 4 229-236

Moore C, Feldman M, Harrison E, Irvan D, Kuntz D, Ross W, Giorgi N, Agrawal A, **Rana S**, Vincent M, Soares J. Analysis of cocaine and metabolites in hair, oral fluid and urine. *Annales de toxicology Analytique* (SFTA) 2005; XVII no. 4: 221-228

Rana S, Garg R. K. Detection of carbamates and their mixtures in commercial formulations by thin layer chromatography. *Intl J Med Toxicol Leg Med* 2002; V no. 1: 17-19

Kaur S, **Rana S,** Garg R.K. Separation and identification of three commonly used anesthetic agents (Lignocaine, Bupivacaine and Propofol) by thin layer chromatography. *Intl J Med Toxicol Leg Med* 2002; IV no. 2: 4-5

Singh O, **Rana S,** Garg R.K. Separation of pyrethroids by thin layer chromatography. *J Forens Med Toxicol* 1999; XVI no 1: 4-9

Kaur J, **Rana S**, Garg R.K. Influence of some storage conditions on the determination of ABH substances from saliva stains *J Forens Med Toxicol* 1999; XV no 2: 1-4

PUBLISHED ABSTRACTS

Macharia LM, Dawson B., and **Rana S.** Incidence of Mitragynine Abuse and Observed Concentrations in Court Ordered Drug Testing Cases. Society of Forensic Toxicologists (SOFT) 2016; (S-05), Dallas, TX.

Uralets VP, **Rana S,** Ross W. Designer stimulants – Evolving abuse patterns. The International association of Forensic Toxicologists (TIAFT) 2015; (THOP27). Florence, Italy.

Rana S, Dawson GB, Macharia L and Raner G. Detection of carboxylated metabolites of XLR-11, UR-144, and their pyrolysis products in oral fluid. *American Academy of Forensic Sciences (AAFS) 2014;* (K-46), Seattle, WA.

Rana S, Dawson GB, Macharia L and Raner G. Detection of carboxylated metabolites of synthetic marijuana in oral fluid. *Society of Forensic Toxicologists (SOFT) 2013;* (P-96), Orlando, FL.

Rana S, Dawson GB, Macharia L, Arends T and Ross W. Monitoring oral fluid for pyrolysis products of XLR-11 and UR-144 as an indication of XLR-11 and UR-144 ingestion. *Society of Forensic Toxicologists (SOFT)* 2013; (S-21), Orlando, FL.

Dawson GB, Raner G and **Rana S**. Pitfalls of analyzing urine specimens for the presence of cycloalkyl functionalized indoles: XLR-11. *Society of Forensic Toxicologists (SOFT) 2013;* (S-20), Orlando, FL.

Arends T, Macharia L, Dawson GB and **Rana S**. Simultaneous analysis of 19 synthetic cannabinoids and their contribution to overall positivity in oral fluid Samples. *Society of Forensic Toxicologists (SOFT) 2013;* (S-20), Orlando, FL.

Rana S, Uralets V and Ross W. Emerging Designer Drugs – To regulate or not to regulate. The International Association of Forensic Toxicologists (TIAFT) 2013; (OE-1). Funchal, Mediera - Portugal.

Rana S, Dawson G, Macharia L, Arends T and Ross W. Monitoring oral fluid for pyrolysis products of XLR-11 and UR-144 as an indication of XLR-11 and UR-144 ingestion. The International Association of Forensic Toxicologists (TIAFT) 2013; (PM-1). Funchal, Mediera - Portugal.

Rana S, Brunson T and Ross W. Simultaneous analysis of 7 synthetic cannabinoids: JWH018, JWH073, JWH250, JWH210, JWH081, RCS4, AM2201 and their contribution to the overall positivity in routine oral fluid specimens. Society of Forensic Toxicologists (SOFT) 2012; (O-73), Boston, MA.

Rana S, Uralets VP and Ross W. Analysis of synthetic cannabinoids JWH018, JWH073, JWH250, JWH210, JWH081, RCS4, AM2201 and their contribution to overall positivity in routine oral fluid specimens. The International Association of Forensic Toxicologists (TIAFT) 2012; (O-73). Hamamatsu, Japan.

Uralets VP, **Rana S** and Ross W. Designer Stimulants: Evolving abuse patterns. The International association of Forensic Toxicologists (TIAFT) 2012; (O72). Hamamatsu, Japan.

Rana S, Uralets VP and Ross W. Routine screening of human urine for 14 new designer stimulants found in “Bath Salts”. Joint meeting of Society of Forensic Toxicologists and The International association of Forensic Toxicologists 2011; (P099). San Francisco, CA.

Rana S, Brunson T and Ross W. Analysis of synthetic cannabinoids JWH018, JWH073 and JWH250 in routine oral fluid specimens. Joint meeting of Society of Forensic Toxicologists and The International association of Forensic Toxicologists 2011; (O68). San Francisco, CA.

Uralets VP, **Rana S** and Ross W. Fluoro- and methyl-ephedrine metabolites in routine urine testing for designer stimulants. Joint meeting of Society of Forensic Toxicologists and The International association of Forensic Toxicologists 2011; (P097). San Francisco, CA.

Rana S, Uralets VP and Ross W. Routine screening of human urine for synthetic cannabinoids by LC-MSMS utilizing spectrum based library search. German Toxicology and Forensic Chemistry (GTFCh) 2011; (V1-mos-52). Mosbach, Germany.

Rana S, Uralets VP and Ross W. Quantitative composition of synthetic cannabinomimetics in “Herbal High” products. Society of Forensic Toxicologists (SOFT) 2010; (P59). Richmond, VA

Rana S, Uralets VP and Ross W. Routine screening of human urine for synthetic cannabinoids by LC-MS/MS utilizing spectrum based library search. Society of Forensic Toxicologists (SOFT) 2010; (S51). Richmond, VA.

Liu H F**, Rana S**, Morris J, Moshin J, Clabaugh M and Wang A. A Screening method for major metabolites of JWH018 and JWH073 in human urine using a hybrid triple quadrupole linear ion trap system. Society of Forensic Toxicologists (SOFT) 2010; (S45). Richmond, VA.

Rana S, Morris J, Ross W, Wang A, Clabaugh M and Liu HF. Identification of the main metabolites of JWH-018, an active ingredient of K2 (Fake Weed) in Human Urine. The International Association of Forensic Toxicologists (TIAFT) 2010; (O-38): 179-180. Bonn, Genmany.

Rana S and Ross W. Incidence of post-collection synthesis and hydrolysis of ethyl glucuronide and ethyl sulfate in random unpreserved urine specimens. The International Association of Forensic Toxicologists (TIAFT) 2010; (O-3): 167. Bonn, Germany.

Rana S and Ross W. A Novel solution for improving instrumental productivity in high throughput labs. Society of Forensic Toxicology (SOFT) 2009; (S27). Oaklahoma.

Rana S, Ross W, Uralets VP and Morgan S. A fast GC/MS method for the analysis of common SSRI's. American Academy of Forensic Science (AAFS) 2009; (K 56): 420-421. Denver, CO.

Rana S and Ross W. Urine ethanol, ethyl glucuronide (EtG) and ethyl sulfate (EtS) – What do the numbers show? Society of Forensic Toxicology (SOFT) 2008; (S34). Phoenix, AZ.

Rana S and Ross W. Positive prevalence rates based on various cutoff concentrations of ethyl glucuronide in a large population of unpreserved random urine specimens. Society of Forensic Toxicology (SOFT) 2008; (P59). Phoenix, AZ.

Sasaki T.A, Bramwell-German C.J, **Rana S** and Ross W.B. A quick LC/MS/MS method for the analysis of common benzodiazepines and opiates. Society of Forensic Toxicology (SOFT) 2008; (P67). Phoenix, AZ.

Rana S, Uralets V P and Ross W. A GC/MS method for the determination of cyclic antidepressants and their metabolites in urine with data comparing free and glucuronide bound drug. The International Association of Forensic Toxicologists (TIAFT) 2008; 20 (S1): 75. Martinique, France.

Rana S, Coulter C, Moore C. Determination of alprazolam in oral fluid. American Academy of Forensic Sciences (AAFS) 2007; (K43) 434-435. San Antonio, TX.

Moore C, Vincent M, Costantino A, Sanders D, **Rana S**, Coulter C. Rapid, sensitive screening of meconium for drugs of abuse. Clinical Chemistry 2006; 52(S6): A67.

Moore C, **Rana S**, Coulter C, Vincent M, Soares J. The detection of 11-nor-delta-9-tetra-hydrocannabinol-9-carboxylic acid (THC-COOH) in hair and urine. American Academy of Forensic Sciences (AAFS) 2006; (K46) 364-365.

Moore C, Lacey J, Baker K. T, Coulter C, Brainard K, Holden F. D, **Rana S**, Vincent M. Analysis of paired blood and oral fluid specimens from randomly selected nighttime drivers. The International Association of Forensic Toxicologists (TIAFT) 2006; AS-o-2: 106-108

Vincent M, Moore C, **Rana S**, Coulter C, Soares J. Conversion of 6-acetylmorphine to morphine during overnight incubation of hair specimens. Society of Hair Testing (SOHT) 2006

Vincent M, Agrawal A, Abolencia E, Nguyen M, Moore C, Coulter C, **Rana S**, Soares J. Evaluation of an aqueous buffer for the recovery of drugs from hair. Society of Hair Testing (SOHT) 2006

WORKSHOPS, PRESENTATIONS AND LECTURES

Synthetic Cannabinoids – A moving target. Lecture at California Association of Toxicologists (CAT) meeting. May 2016. Lake Tahoe, NV

Kratom - A drug of concern. Lecture at California Association of Toxicologists (CAT) meeting. May 2016. Lake Tahoe, NV

Toxicology of designer benzodiazepines and opioids. Workshop Chair. Society of Forensic Toxicology (SOFT), Oct. 2016. Dallas, TX.

Pharmacology and toxicology of synthetic cathinones and phenylethylamines. Workshop Chair. Society of Forensic Toxicology (SOFT), Oct. 2015. Atlanta, GA.

Cathinones and Cannabimimetics: Techniques, challenges and interpretive considerations". Lecture in Workshop W1. American Academy of Forensic Sciences (AAFS), Feb 17th, 2014. Seattle, WA.

Designer Drug Detection in Forensic Toxicology: From basics to brilliant! American Academy of Forensic Sciences (AAFS) Workshop W1 Chair, Feb 17th, 2014. Seattle, WA.

Designer Drugs – Why and how to detect. Training provided to Sonoma County Probation Department, Santa Rosa, CA. October 15, 2013.

"Spice"- Detection in oral fluid. Training provided to the Drug Intelligence and Forensic Center, Ministry of Public Security of P. R. C. Haidian District, Beijing, China. October 12th, 2013.

Designer Drugs – To regulate or not to regulate? Training provided to the Drug Intelligence and Forensic Center, Ministry of Public Security of P. R. C. Haidian District, Beijing, China. October 11th, 2013

"Bath Salts"- Evolving abuse patterns and detection in biological fluids. Training provided to the Drug Intelligence and Forensic Center, Ministry of Public Security of P. R. C. Haidian District, Beijing, China. October 11th, 2013

"Spice" - Evolving abuse patterns and detection in biological fluids. Training provided to the Drug Intelligence and Forensic Center, Ministry of Public Security of P. R. C. Haidian District, Beijing, China. October 10th, 2013

Molly and Other Designer Drugs – How to detect them? Training provided to the Drug Intelligence and Forensic Center, Ministry of Public Security of P. R. C. Haidian District, Beijing, China. October 10th, 2013

"Spice": Evolving abuse patterns and detection in biological fluids. ABSCIEX Users Meeting, American Society of Mass Spectrometry (ASMS), May 20th, 2012. Vancouver, Canada.

Components of "Spice": Stability in oral fluid and positivity rates in routine specimens. Workshop #12, Society of Forensic Toxicologists (SOFT), Sept 27th, 2011. San Francisco, CA

Components of "Spice": Trends in the US and detection in urine. Workshop #12, Society of Forensic Toxicologists (SOFT), Sept 27th, 2011. San Francisco, CA

Large Scale Testing for Alcohol and its Markers: Ethyl glucuronide (EtG) and ethyl sulfate (EtS). Satellite Symposium at German Toxicology and Forensic Chemistry (GTFCh) Meeting, April 13th 2011. Mosbach, Germany.

Synthetic Cannabinoids in Oral Fluid: Routine screening. Workshop at California Association of Toxicologists (CAT) Meeting, May 7th 2011. Napa, CA.

Synthetic Cannabinoids in Urine: Routine screening. Workshop at California Association of Toxicologists (CAT) Meeting, May 6th 2011. Napa, CA

K2- Fake Weed, Real Drug – Metabolite Identification using QTRAP system and high resolution, exact mass LC/MS/MS technology. Annual Users meeting ASMS 2010, Salt Lake City, Utah. May 23, 2010

Alcohol and Drug Testing: Interpretation and effective use of screens for substance of abuse. Marin County, San Rafael, CA. March 4, 2010

Alcohol and Drug Testing: Interpretation and effective use of screens for substance of abuse. Sonoma County, Santa Rosa, CA. December 16, 2009.

Drug and Alcohol Testing –Special reference to ethyl glucuronide. Napa County, Napa, CA. November 4, 2009.

Drug and Alcohol Testing – Special reference to ethyl glucuronide. Santa Clara County - Pretrial, Santa Clara, CA. March 12, 2009.

Drug and Alcohol Testing –Special reference to ethyl glucuronide. Washington County, Oregon. November 6, 2008.

Urine Ethanol, Ethyl Glucuronide (EtG) and Ethyl Sulfate (EtS) – What do the numbers show? Society of Forensic Toxicology (SOFT). October 30, 2008.

Drug and Alcohol Testing –Special reference to ethyl glucuronide. Treatment Court Training Day, Orange County Probation department. March 4, 2008.

Drug testing services – Validity of on-site screening devices v/s lab based testing. Treatment Associates, Inc. San Antonio, Texas. June 13, 2008.

Wayne B. Ross

CURRICULUM VITAE

EDUCATION:

M.C.L.S. University of California at San Francisco, San Francisco, CA.
MASTER'S IN CLINICAL LABORATORY SCIENCE – Concentrations: Clinical Chemistry and Analytical Toxicology, April 1986.

B.S. California State Polytechnic Univ., San Luis Obispo, CA.
BIOLOGICAL SCIENCE – Concentration: Medical Laboratory Technology, June 1973

PROFESSIONAL EXPERIENCE:

CHIEF TOXICOLOGIST: Redwood Toxicology Laboratory, Santa Rosa, CA. ; 07/94 – Present.
Responsible for planning, organizing, supervising, and coordinating the personnel, methods, and procedures for a high volume urine and oral fluid drug testing laboratory. Duties include maintaining the technical SOP, certifying ongoing compliance to regulations as mandated by the California Dept. of Health (Title 17) and Dept. of Health and Human Services (Health Care Financing Administration) CLIA '88 regulations, evaluate and validate all laboratory methods, and direct GC/MS Dept.. Duties also include reviewing and certifying analytical results for reporting purposes.

Additional responsibilities include consulting with and interpreting data for many criminal justice agencies such as District Attorney's, County Counsel, Public Defender's, Sheriff and Police Departments, U.S. Attorney's Office, and Parole and Probation Departments. Also provide technical support to drug rehabilitation centers, methadone maintenance clinics, child protective services, etc.

Testified and qualified as an expert witness in excess of 200 times in Superior, Municipal, and Juvenile Courts throughout California and several other states, as well as Federal Court -- specifically in regard to interpretation and explanation of forensic and clinical toxicological analytical methods and data as performed on urine and oral fluid., including the pharmacokinetics and pharmacodynamics of illegal and prescribed drugs.

SUPERVISING CLINICAL TECHNOLOGIST / CHIEF TOXICOLOGIST: Redwood Medical Laboratory, Santa Rosa, CA.; 06/76 – 07/94.

Responsibilities included ensuring compliance to all local, state and federal regulations; maintenance of quality control and quality assurance; manage and perform testing in all areas of clinical laboratory including: Therapeutic Drug Monitoring and Toxicology, RIA, Clinical and Special Chemistry, Hematology, Blood Banking and Serology, Microbiology, Parasitology, Coagulation, etc.

In addition performed technical development and management of all aspects of a national drugs of abuse testing program to include: method development, quality assurance and quality control, performance of initial and confirmatory testing, and provide expert witness testimony.

CHIEF TECHNOLOGIST: Physician Office Clinical Laboratory, Santa Rosa, CA.; 06/75 – 06/76

Managed clinical laboratory for hematology / oncology group practice.

GENERAL TECHNOLOGIST / TOXICOLOGIST: Central Pathology Laboratory, Santa Rosa, CA. 08/74 – 06/75

Completed one year traineeship for licensure as a State of California Clinical Laboratory Scientist. Training heavily emphasized clinical and forensic toxicology.

CERTIFICATIONS / LICENSE:

California State License - Clinical Laboratory Scientist (Includes the practice of Clinical and Forensic Toxicology) - License [redacted]

American Association of Bioanalysts Board of Registry – Medical Technologist (Includes the practice of Clinical Toxicology).

Department of Health and Human Services, Health Care Financing Administration, CLIA 88 – Qualified as a Clinical Laboratory Technical Consultant, Technical Supervisor, and General Laboratory Supervisor (Includes the practice of Clinical and Forensic Toxicology).

PROFESSIONAL AFFILIATIONS:

Fellow - National Academy of Clinical Biochemistry
Member - American Association of Clinical Chemistry
Member - American Academy of Forensic Sciences
Member - Society of Forensic Toxicologists
Member - California Association of Toxicologists
Associate Member - American Association of Bioanalysts
Member - California Narcotic Officer's Association
Diplomate - American Board of Forensic Examiners International
Fellow - American College of Forensic Examiners International

CONTINUING EDUCATION / PROFESSIONAL MEETINGS

Society of Forensic Toxicologist's Annual Meeting; Atlanta, GA; 9 CEU's (10/2015)
California Association of Toxicologist's Semi-Quarterly Meeting; San Francisco, CA; 13.75 CEU's (5/2015).
California Association of Toxicologist's Semi-Quarterly Meeting; Sacramento, CA; 12 CEU's (5/2014).
American Academy of Forensic Sciences Annual Meeting; Orlando, FL.. (2/2014)
Society of Forensic Toxicologist's Annual Meeting; Orlando, FL; 9 CEU's (10/2013)
American Association for Clinical Chemistry Annual Meeting; Houston, TX; 14.5 CEU's (7/2013)
American Academy of Forensic Sciences Annual Meeting; Washington D.C.: 17 CEU's (2/2013)
Society of Forensic Toxicologist's Annual Meeting; Boston, MA; 25.0 CEU's; (7/12)
California Association of Toxicologist's Semi-Quarterly Meeting and All Things Cannabis Workshop; San Jose, CA; 12.5 CEU's (5/12).
American Academy of Forensic Sciences Annual Meeting; Atlanta, GA.; 20.0 CEU's (2/2012)
Society of Forensic Toxicologist's Annual Meeting; San Francisco, CA; 13.5 CEU's; (9/11)
California Association of Toxicologist's Semi-Quarterly Meeting and The Future of Drug Abuse/Designer Drugs Workshop; Napa, CA; 12 CEU's (5/11).
American Academy of Forensic Sciences Annual Meeting; Chicago, IL.; 17.5 CEU's (2/2011)
Society of Forensic Toxicologist's Annual Meeting; Richmond, VA; 25.5 CEU's; (10/10)
American Association for Clinical Chemistry Annual Meeting; Anaheim, CA; 10.5 CEU's (7/2010)
American Academy of Forensic Sciences Annual Meeting; Seattle, WA.; 22 CEU's (2/2010)
Society of Forensic Toxicologist's Annual Meeting; Oklahoma City, OK; 20.5 CEU's; (10/09)
American Association for Clinical Chemistry Annual Meeting; Chicago, IL; 13.5 CEU's (7/09)
California Association of Toxicologist's Semi-Quarterly Meeting and Pharmacology for Toxicologist's Workshop; San Francisco, CA; 13 CEU's (1/09).
Society of Forensic Toxicologist's Annual Meeting; Phoenix, AZ; 24 CEU's; (10/08)
American Academy of Forensic Sciences Annual Meeting; Washington D.C.; 18.5 CEU's (2/2008)
California Association of Toxicologist's Workshop & Quarterly Meeting; Monterey, CA; 12 CEU's (11/07)
American Association for Clinical Chemistry Annual Meeting; San Diego, CA; 17 CEU's (7/07)
California Association of Toxicologist's Workshop & Semi-Quarterly Meeting; Phoenix, AZ; 12 CEU's (6/07)
American Academy of Forensic Sciences Annual Meeting; San Antonio, TX; 17 CEU's (2/2007)
California Association of Toxicologist's Workshop & Quarterly Meeting; San Francisco; 12 CEU's (6/06)
Society of Forensic Toxicologist's Annual Meeting; Nashville, TN; 22 CEU's; (10/05)
California Association of Toxicologist's Workshop & Quarterly Meeting; Las Vegas, NV; 12 CEU's (8/05)
Society of Forensic Toxicologist's / The International Association of Forensic Toxicologist's Joint Annual Meeting; Washington D.C.; 23 CEU's; (9/04)

American Academy of Forensic Sciences Annual Meeting; Dallas, TX; (2/2004)
Society of Forensic Toxicologist's Annual Meeting; Portland, OR; 23.25 CEU's; (10/03)
California Association of Toxicologist's Workshop & Quarterly Meeting; Santa Rosa, CA; 12 CEU's (8/03)
California Association of Toxicologist's Quarterly Meeting; Oakland, CA; 5.5 CEU's (2/2003)
Society of Forensic Toxicologist's Annual Meeting; Dearborn, MI. (10/2002)
California Association of Toxicologist's Quarterly Meeting; San Jose, CA ; 6.5 CEU's (8/2002)
Society of Forensic Toxicologist's Annual Meeting; New Orleans, LA; 15.5 CEU's (10/2001)
California Association of Toxicologist's Quarterly Meeting; Berkeley, CA; 4.5 CEU's (8/2001) – Co-Host
American Academy of Forensic Sciences Annual Meeting; Seattle, WA; 23.25 CEU's (2/2001)
California Association of Toxicologist's Quarterly Meeting; South San Francisco, CA; 6 CEU's (2/2001)
American Association for Clinical Chemistry (TDM & Toxicology); 18 CEU's (2000)
Society of Forensic Toxicologist's Annual Meeting; Milwaukee, WI (10/2000)
American Academy of Forensic Sciences Annual Meeting; Reno, NV (2/2000)
American Association for Clinical Chemistry (TDM & Toxicology); 24 CEU's (1999)
AACC Laboratory Automation Conference; Philadelphia. PA ,14 CEU's (11/99)
American Academy of Forensic Sciences Annual Meeting; Orlando, FL (2/99)
American Association for Clinical Chemistry (TDM & Toxicology); 20 CEU's (1998)
California Association of Toxicologist's Quarterly Meeting; San Francisco, CA (2/98)
American Academy of Forensic Sciences Annual Meeting; San Francisco, CA (2/98)
American Association for Clinical Chemistry (TDM & Toxicology); 22 CEU's (1997)
Society of Forensic Toxicologist's Annual Meeting; Salt Lake City, UT (10/97)
California Association of Toxicologist's Quarterly Meeting; San Jose, CA (8/97)
California Association of Toxicologist's Quarterly Meeting; Oakland, CA (2/97)
American Association for Clinical Chemistry (TDM & Toxicology); 20 CEU's (1996)
California Association of Toxicologist's Quarterly Meeting; South San Francisco, CA (11/96)
Society of Forensic Toxicologist's Annual Meeting; Denver, CO. (10/96)
California Association of Toxicologist's Quarterly Meeting; North Lake Tahoe, CA (5/96).
American Association for Clinical Chemistry (TDM & Toxicology); 20 CEU's (1995)
Society of Forensic Toxicologist's Annual Meeting; Baltimore, MD. (10/95)
California Association of Toxicologist's Quarterly Meeting; Napa, CA (8/95).
American Association for Clinical Chemistry (TDM & Toxicology); 24 CEU's (1994)
American Association for Clinical Chemistry (TDM & Toxicology); 24 CEU's (1993)

TRAINING: (Abbreviated List)

"Pharmacognosy for the Forensic Toxicologist", Society of Forensic Toxicologists.
"Pharmacology and Toxicology of Synthetic Cathinones and Phenethylamines", Society of Forensic Toxicologists.
"Designer Drug Detection in Forensic Toxicology: From Basics to Brilliant!", American Academy of Forensic Sciences.
"Novel Psychoactive Substances: Pharmacology, Toxicology, Psychiatry and Case Reports", American Academy of Forensic Sciences.
"Sports Drug testing and Forensic Toxicology Laboratories", American Association for Clinical Chemistry.
"Designer Drugs and Mass Spectrometry", American Association for Clinical Chemistry.
"Developments in Emerging and Designer Drug Markets 2013"; Academy of Forensic Sciences.
"Beyond the Numbers: An Objective Approach to Forensic Toxicological Interpretation", Academy of Forensic Sciences.
"Strategies for Expanding DUID Testing – Is Oral Fluid the Way Ahead?", Society of Forensic Toxicologists.
"Opioids – 21st Century Killers", Society of Forensic Toxicologists.
"Pharmacodynamics & Pharmacokinetics of Acute & Chronic Cannabis", California Association of Toxicologists.
"Preparation and Strategic Planning for Accreditation of Forensic Laboratories Based on the ISO/IEC 17025 International Standard", American Academy of Forensic Sciences.
"Applications of Oral Fluid Drug Testing", Society of Forensic Toxicologists.
"Spice: detection in Various Biological Matrices", Society of Forensic Toxicologists.
"Method Validation and Estimating the Uncertainty of Measurements in the Modern Forensic Laboratory", American Academy of Forensic Sciences.
"K2 and Beyond: A Synthetic Cannabinoid Primer", Academy of Forensic Sciences.
"Marijuana Pharmacology", Society of Forensic Toxicologists.
"Pain Management: Clinical Perspectives and the Role of the Clinical Laboratory", American Association for Clinical Chemistry.

“Drugs of Abuse Testing in Alternative Specimens: Advantages and Pitfalls”, American Association for Clinical Chemistry.
“Role of Laboratory in the Science of Drinking: From Blood Alcohol Levels, Markers of Alcohol Abuse to Pharmacogenomics”, American Association for Clinical Chemistry.
“Attorneys and Scientists in the Courtroom: Bridging the Gap”, Academy of Forensic Sciences.
“Strengthening Forensic Science in the United States: A Path Forward – The Judgees’ Perspective”, American Academy of Forensic Sciences.
“Newer Prescription Drugs: Impairment Potential & Identified Polypharmacies”, Society of Forensic Toxicologists.
“Crawford Motions: The Right to Confrontation & How Recent Rulings May Affect Forensic Laboratory Management and Expert Testimony, Society of Forensic Toxicologists.
“How to Fulfill the CLIA Requirements for Calibration, Calibration Verification, and Reportable Range” American Association for Clinical Chemistry.
“Concepts and Practices in the Evaluation of Laboratory Methods”, American Association for Clinical Chemistry.
“Pharmacobasics: An Introduction to Pharmacology for Toxicologist’s”, California Association of Toxicologists.
“Effects of Drugs on Human Performance and Behavior – A Borkenstein Sampler”, Society of Forensic Toxicologists.
“Pain Management and Addiction”, Society of Forensic Toxicologists.
“Marijuana Induced Psychosis”, American Academy of Forensic Science.
“Postmortem Toxicology: Interpretation of Drug Concentrations in Hair”, American Academy of Forensic Science.
LC/MS/MS Instrumentation and Applications - 5 Workshops – American Association for Clinical Chemistry.
“Newer Analytical Techniques: Applications in Forensic Toxicology”, American Academy of Forensic Sciences.
“Improving the Toxicological Investigation of Drug-Facilitated Sexual Assault and Other Crimes”, American Academy of Forensic Sciences.
“Case Studies in DUID: Numbers, Signs, Symptoms, and Beyond”, Society of Forensic Toxicologists.
“Laboratory Experiences with Oral Fluid Testing”, California Association of Toxicologists.
“Oral Fluid Drug Testing”, California Association of Toxicologists.
FBI Laboratory Symposium on Forensic Toxicology, Society of Forensic Toxicologists and The International Association of Forensic Toxicologists, FBI and DOJ.
“Ephedrine: Drug or Supplement”, American Academy of Forensic Sciences.
“Application of the Principles of Pharmacology and Pharmacokinetics …”, American Academy of Forensic Sciences.
“Tryptamines and Other Psychotropic Substances…”, American Academy of Forensic Sciences.
“Practical Applications for LCMS in Routine Toxicology Testing”, Society of Forensic Toxicologists.
“Toxicology in the Emergency Room”, Society of Forensic Toxicologists.
“Developments in Regulated Drug Testing”, Society of Forensic Toxicologists.
“Principles of Sample Preparation”, Society of Forensic Toxicologists.
“Club Drugs & Drug-Facilitated Sexual Assault”, Society of Forensic Toxicologists.
“DUID – From Research to the Courts”, Society of Forensic Toxicologists.
“Urine Testing and Human Performance”, Society of Forensic Toxicologists.
“Clinical Toxicology”, Society of Forensic Toxicologists.
“Adulterant Testing”, Society of Forensic Toxicologists.
“Advances in Toxicological Investigation of Drug-Facilitated Sexual Assault”, American Academy of Forensic Sciences.
“AAFS Toxicology Section Drugs and Driving Committee”, American Academy of Forensic Sciences.
“Ethical Problems Facing the Expert Witness”, American Academy of Forensic Sciences.
“The Agony of Ecstasy”, American Academy of Forensic Sciences.
“Benzodiazepines: Pharmacology & Analytical Challenges”, Society of Forensic Toxicologists.
“Marijuana Forensic Symposium”, Society of Forensic Toxicologists.
“Forensic Toxicology of Opiate Alkaloids and Synthetic Analgesics”, American Academy of Forensic Sciences
“Pharmacology and Toxicology of Buprenorphine”, American Academy of Forensic Sciences
“Presenting Scientific Evidence in Court: Meeting the Daubert Standard for Reliability”, American Academy of Forensic Sciences
“How To Be a Better Expert Witness”, American Academy of Forensic
“Marijuana: A Forensic Symposium”, American Academy of Forensic Sciences
“The Effects of Alcohol and Drugs on Human Performance and Behavior”, American Academy of Forensic Sciences .
“Methamphetamine: Synthesis, Pharmacology, Analysis, and Toxicology”, American Academy of Forensic Sciences .
“Laboratory Accreditation: Exploring the Alternatives”, American Academy of Forensic Sciences .
“Forensic Expert Witness Court Testimony”, American Academy of Forensic Sciences .

"Fundamentals of Alcohol Testing and Interpretation", Society of Forensic Toxicologists
"Automated Sample Preparation for Chromatographic and Mass Spectra Analysis", Society of Forensic Toxicologists
"Forensic Applications of LC/MS", Society of Forensic Toxicologists.
"Capillary Chromatography", Society of Forensic Toxicologists
"New Concepts in Forensic Urine Drug Testing", Society of Forensic Toxicologists.
"Use of LIMS ia a Forensic Laboratory", Society of Forensic Toxicologists.
"Workshop on Stimulant Induced Impairment", California Association of Toxicologists
"Drugs and Driving: Current Pharmacologic Issues", Society of Forensic Toxicologists
"Current Issues in Regulated Urine Drug Testing", Society of Forensic Toxicologists.
"Fundamentals of Forensic Toxicology: A Basic Course", Society of Forensic Toxicologists

PUBLICATIONS:

Victor Uralets, Sumandeep Rana, Stewart Morgan and **Wayne Ross**., "Testing for Designer Stimulants: Metabolic Profiles of 16 Synthetic Cathinones Excreted Free in Human Urine", Journal of Analytical Toxicology, Vol. 38, No. 5, pp. 233 – 241, June 2014.

Victor Uralets, Mike App, Sumandeep Rana, Stewart Morgan, and **Wayne Ross**, "Designer Phenethylamines Routinely Found in Human Urine: 2-Ethylamino-1-Phenylbutane and 2-Amino-1-Phenylbutane", Journal of Analytical Toxicology, Vol. 38, No. 2, pp. 106 – 109, March 2014.

Rana, S., Uralets, V., and **Ross, W**., "A New Method for Simultaneous Determination of Cyclic Antidepressants and their Metabolites in Urine Using Enzymatic Hydrolysis and Fast GC-MS", Journal of Analytical Toxicology, Vol. 32, No. 5, pp. 355 – 363, June 2008.

Rohrig, T.P., Huber, C. Goodson, L., and **Ross, W**., "Detection of Ethyl Glucuronide in Urine following the Application of Germ-X", Journal of Analytical Toxicology, Nov/Dec 2006, Letter to the Editor.

Moore, C., **Ross, W**., Coulter, C., Adams, L., Rana, S., Vincent, M., and Soares, J. "Detection of the Marijuana Metabolite 11-Nor-delta-9-Carboxylic Acid in Oral Fluid Specimens, and its Contribution to Positive Results in Screening Assays", Journal of Analytical Toxicology, Vol. 30, No.7, pp. 413 – 418, September 2006.

Moore C, Feldman M, Harrison E, Irvan D, Kuntz D, **Ross W**, Giorgi N, Agrawal A, Rana S, Vincent M,Soares J. Analysis of cocaine and metabolites in hair, oral fluid and urine. *Annales de ToxicologieAnalytique (SFTA) XVII no. 4 221 - 228 (2005)*

Moore C, Feldman M, Giorgi N, **Ross W**, Harrison E, Irvan D, Kuntz D, Agrawal A, Rana S, Vincent M, Soares J. Analysis of amphetamines in hair, oral fluid and urine. *Annales de Toxicologie Analytique (SFTA) XVII no. 4 229 - 236 (2005)*

Meeker, J.E., Mount, A.M., and **Ross, W.B**., "Detection of Drug Abuse by Health Professionals", Occupational Health and Safety, 2002

Ross, W.B., "Specimen Collection for Drugs of Abuse Testing", Treatment Centers Magazine, 1992.

PRESENTATIONS:

Coulter, C, Garnier, M, Moore, C., and **Ross, W.** THC and THC-COOH in Oral Fluid: Immunoassay and LC/MS/MS, Society of Forensic Toxicologists Annual Meeting, 2015 (P116), Atlanta, GA.

Rana,S, Uralets V, **Ross, W**, Emerging Designer Drugs – To Regulate or Not To Regulate. The International Association of Forensic Toxicologists (TIAFT) 2013; (OE-1). Funchal, Medeira, Portugal.

Rana S, Dawson G, Macharia L, Arends T, and **Ross W**. Monitoring Oral Fluid for Pyrolysis Products of XLR-11 and UR-144 as an Indication of XLR-11 and UR-144 Ingestion. The International Association of Forensic Toxicologists (TIAFT) 2013; (PM-1). Funchal, Medeira, Portugal.

Sumandeep Rana, Tara Brunson, and **Wayne Ross**. Incomplete Recovery of Codeine in Urine Using Common

Enzymatic Hydrolysis Procedures, American Academy of Forensic Sciences, 2013; (K57).

Sumandeep Rana, Tara Brunson, and **Wayne Ross**. Analysis of Synthetic Cannabinoids JWH018, JWH073, JWH250, JWH210, JWH081, RCS-4, AM2201 and Their Contribution to the Overall Positivity in Routine Oral Fluid Specimens, The International Association of Forensic Toxicologists (TIAFT) 2012; (O-73).

Victor Uralets, Sumandeep Rana, and **Wayne Ross**. Designer Stimulants – Evolving Abuse Patterns, The International Association of Forensic Toxicologists (TIAFT) 2012; (O-72).

Victor Uralets, Sumandeep Rana, and **Wayne Ross**, Excretion Profiles for 13 Designer Synthetic Cathinones in Human Urine. Interpretive value of β-hydroxy Metabolites, MSACL Annual Meeting, 2012

Sumandeep Rana, Victor Uralets and **Wayne Ross**, Routine Screening of Human Urine for 14 New Designer Stimulants Found in "Bath Salts" Using GC/MS, Society of Forensic Toxicologists, Annual Meeting, 2011; (P099)

Victor Uralets, Sumandeep Rana and **Wayne Ross**, Fluoro- and Methyl-Ephedrine Metabolites in Routine Urine Testing for Designer Stimulants, Society of Forensic Toxicologists, Annual Meeting, 2011; (P097).

Sumandeep Rana, Tara Brunson and **Wayne B. Ross**, Quantitative Analysis of Synthetic Cannabinoids JWH018, JWH073 and JWH250 in Routine Oral Fluid Specimens, Society of Forensic Toxicologists, Annual Meeting, 2011; (O68).

Sumandeep Rana, Victor P. Uralets, Tara Brunson and **Wayne B. Ross,** Quantitative Composition of Synthetic Cannabinoids in "Herbal High" Products. Society of Forensic Toxicologists, Annual Meeting, 2010; (P59).

Sumandeep Rana, Victor P. Uralets, and **Wayne B. Ross**, Routine Screening of Human Urine for Synthetic Cannabinoids by LC-MS/MS Utilizing Spectrum Based Library Search. Society of Forensic Toxicologists, Annual Meeting, 2010; (S51)

Rana S, Morris J, **Ross W**, Wang A, Clabaugh M and Liu HF. Identification of the main metabolites of JWH-018, an active ingredient of K2 (Fake Weed) in Human Urine. The International Association of Forensic Toxicologists (TIAFT) 2010; (O-38): 179-180

Rana S and **Ross W**. Incidence of Post-Collection Synthesis and Hydrolysis of Ethyl Glucuronide and Ethyl Sulfate in Random Unpreserved Urine Specimens. The International Association of Forensic Toxicologists (TIAFT) 2010; (O-3): 167

Tania A. Sasaki, Claire J. Bramwell-German, Sumandeep Rana, **Wayne B. Ross**, A Quick LC/MS/MS Method for the Analysis of Common Benzodiazepines and Opiates, American Academy of Forensic Sciences, Annual Meeting, 2009

Sumandeep Rana, **Wayne B. Ross**, and Victor P. Uralets, A Fast GC/MS Method for the Analysis of Common Selective Serotonin Reuptake Inhibitors, American Academy of Forensic Sciences, Annual Meeting, 2009

Sumandeep Rana and **Wayne B. Ross**, Positive Prevalence Rates Based on Various Cutoff Concentrations of Ethyl Glucuronide in a Large Population of Unpreserved Random Urine Specimens, Society of Forensic Toxicologists, Annual Meeting, 2008.

Sumandeep Rana and **Wayne B. Ross,** Urine Ethanol, Ethyl Glucuronide (EtG), and Ethyl Sulfate (EtS) – What do the Numbers Show?, Society of Forensic Toxicologists, Annual Meeting, 2008.

Tania A. Sasaki, Claire J. Bramwell-German, Sumandeep Rana, and **Wayne B. Ross**, A Quick LC/MS/MS Method for the Analysis of Common Benzodiazepines and Opiates, Society of Forensic Toxicologists, Annual Meeting, 2008.

Moore, C., Rana, S., Coulter, C., Vincent, M., Soares, J., **Ross, W**., and Giorgi, N., Detection of 11-nor-delta 9-THC-Carboxylic Acid (THC-COOH) in Hair and Urine, American Academy of Forensic Sciences, Annual Meeting,

2006

Feldman, M., Harrison, E., Moore, C., Giorgi, N., **Ross, W**., Irvan, D., Kuntz, D., Agrawal, A., Rana, S., Vincent, M., and Soares, J., Methamphetamine and Metabolites in Hair, Oral Fluid, and Urine, Society of Forensic Toxicologists, 35th Annual Meeting, 2005.

Moore, C.,Feldman, M., Harrison, E., , Giorgi, N., **Ross, W**., Irvan, D., Kuntz, D., Agrawal, A., Rana, S., Vincent, M., and Soares, J., Cocaine and Metabolites in Hair, Oral Fluid, and Urine, Society of Forensic Toxicologists, 35th Annual Meeting, 2005.

Moore, C.,Feldman, M., Harrison, E., , Giorgi, N., **Ross, W**., Irvan, D., Kuntz, D., Agrawal, A., Rana, S., Vincent, M., and Soares, J., Cut-offs for Cocaine and Metabolites in Hair, Workshop of the Society of Hair Testing, Strasbourg, France, Sept., 2005.

Moore, C.,Feldman, M., Harrison, E., , Giorgi, N., **Ross, W**., Irvan, D., Kuntz, D., Agrawal, A., Rana, S., Vincent, M., and Soares, J., Cut-offs for Methamphetamne in Hair, Workshop of the Society of Hair Testing, Strasbourg, France, Sept., 2005.

AWARDS:

Clinical Chemist Recognition Award – 2013: For demonstration of professional development through continuing education in clinical chemistry - American Association of Clinical Chemistry (Includes clinical and forensic toxicology).

Clinical Chemist Recognition Award – 2012: For demonstration of professional development through continuing education in clinical chemistry - American Association of Clinical Chemistry (Includes clinical and forensic toxicology).

Clinical Chemist Recognition Award – 2011: For demonstration of professional development through continuing education in clinical chemistry - American Association of Clinical Chemistry (Includes clinical and forensic toxicology).

Clinical Chemist Recognition Award – 2009: For demonstration of professional development through continuing education in clinical chemistry - American Association of Clinical Chemistry (Includes clinical and forensic toxicology).

Clinical Chemist Recognition Award – 2007: For demonstration of professional development through continuing education in clinical chemistry - American Association of Clinical Chemistry. (Includes clinical and forensic toxicology).

Clinical Chemist Recognition Award – 2004: For demonstration of professional development through continuing education in clinical chemistry - American Association of Clinical Chemistry. (Includes clinical and forensic toxicology).

D8-tetrahydrocannabinol	5,000	Cannabidiol	>100,000
Tricyclic Antidepressant			
Nortriptyline	1,000	Promazine	1,500
Nordoxepin	2,000	Desipramine	400
Trimipramine	2,000	Doxepin	3,000
Amitriptyline	1,500	Maprotiline	2,000

D. Interference

The following compounds were evaluated for potential positive and/or negative interference with the DrugCheck Drug Screen Cup. All compounds were dissolved in the drug control solutions with 50% below and 50% above cutoff concentrations and tested with DrugCheck Drug Screen Cup. An unaltered sample was used as a control.

No positive interference or negative interference was found for the following compounds when tested at concentrations up to 100 µg/mL.

Acetaminophen
Acetone
Albumin
Acetylsalicylic acid
Ampicillin
Ascorbic Acid
Aspartame
Aspirin
Atropine
Benzocaine
Bilirubin
Caffeine
Chloroquine
(+)-Chlorpheniramine
(+/-)-Chlorpheniramine
Creatine
Dexbrompheniramine
Dextromethorphan
Diphenhydramine
Dopamine
(+/-)-Epinephrine
Erythromycin
Ethanol
Furosemide
Glucose
Guaiacol Glyceryl Ether
Hemoglobin
Ibuprofen
(+/-)-Isoproterenol
Ketamine
Levorphanol
Lidocaine
Myoglobin
(+)-Naproxen
Niacinamide
Nicotine
(+/-)-Norephedrine
Oxalic Acid
Penicillin-G
Pheniramine
Phenothiazine
l-Phenylephrine
b-Phenylethylamine
Procaine
Pseudoephedrine
Quinidine
Ranitidine
Riboflavin
Sertraline
Sodium Chloride
Sulindac
Theophylline
Tyramine
4-Dimethylaminoantipyrine
(1R,2S)-(-)-N-Methyl-Ephedrine

E. Effect of Specimen pH

Drug sample solutions with 50% below and 50% above cutoff concentrations were adjusted to pH 4-9 and tested using the DrugCheck Drug Screen Cup. An unaltered sample was used as a control. The results demonstrate that varying ranges of specimen pH do not interfere with the performance of the test.

F. Effect of Specimen Specific Gravity

Drug sample solutions with 50% below and 50% above cutoff concentrations were adjusted to specific gravity 1.003-1.04 and tested using the DrugCheck Drug Screen Cup. An unaltered sample was used as a control. The results demonstrate that varying ranges of specimen specific gravity do not interfere with the performance of the test.

ADULTERATION TESTS

Adulteration of urine samples may cause erroneous results in drugs of abuse tests by either interfering with the drug screening test and/or destroying the drugs in the urine. Dilution of urine with water is probably the simplest urine adulteration method. Bleach, vinegar, eye drops, sodium bicarbonate, sodium nitrite, Drano, soft drinks and hydrogen peroxide are examples of adulterants used to adulterate urine samples. It is important to insure the integrity of urine samples in drugs of abuse testing.

The DrugCheck Drug Screen Cup with adulteration test is based on the color response of chemical indicators in the presence of adulterants. Creatinine (CR), nitrite (NI), pH, bleach/oxidant (OX), and specific gravity (SG) are tested to determine the integrity of urine samples.

CR: Creatinine reacts with a creatinine indicator in an alkaline medium to form a purplish-brown color complex. The color intensity is directly proportional to the concentration of creatinine. A urine sample with a creatinine concentration of less than 20 mg/dL is indicative of adulteration.

NI: Nitrite reacts with the reagent's aromatic amine to form a diazonium salt which couples with an indicator to yield a pink-red/purple color complex. A urine sample containing nitrite at a level greater than 15 mg/dL is considered adulterated.

pH: The pH determination of urine sample is based on the color change of an indicator in an acidic or basic medium. Normal urine pH ranges from 4 to 9. A urine pH below 4 or above 9 indicates adulteration with acid or base to the sample.

OX: Bleach or other oxidizing agents react with an oxidant indicator to form a color complex. Observation of a blue-green, brown, or orange color indicates adulteration with bleach or other oxidizing agents.

SG: The specific gravity test is based on the pKa change of certain pretreated polyelectrolytes in relation to the ionic concentration. In the presence of an indicator, the color changes from dark blue to blue-green in urine of low ionic concentration to green and yellow-green in urine of higher ionic concentration. A urine specific gravity below 1.005 or above 1.025 is considered abnormal.

PERFORMING THE ASSAY WITH ADULTERATION TEST

Preparation

1. If specimen, control, or test devices have been stored at refrigerated temperatures, allow them to warm to room temperature before testing.

2. Do not open test device pouch until ready to perform the test.

Testing (Please refer to the color chart)

Semi-quantitative results are obtained by visually comparing the reacted color blocks on the adulteration strips to the printed color blocks on the color chart. No instrumentation is required.

1. Remove the test cup from the sealed pouch.

2. Hand the cup to the individual being tested.

3. Collect the urine into the cup. A minimum of 30 mL is recommended.

4. Secure the test device cap to the specimen cup. The cup must be returned immediately to the collector.

5. Read the adulteration strips between 3 and 5 minutes. Compare the colors on the adulteration strip to the enclosed color chart. If the specimen indicates adulteration, refer to your Drug Free Policy for guidelines on adulterated specimens. We recommend not to interpret the drug test results and either retest the urine or collect another specimen.

6. Authorized personnel should remove the tear-off label.

7. Read results of the drugs of abuse tests at 5 minutes. Do not interpret results after 10 minutes.

BIBLIOGRAPHY OF SUGGESTED READING

1. Baselt, R. C., Disposition of Toxic Drugs and Chemicals in Man, Biomedical Publications, Davis, CA, 1982.

2. Urine testing for Drugs of Abuse. National Institute on Drug Abuse (NIDA), Research Monograph 73, 1986.

3. Fed. Register, Department of Health and Human Services, Mandatory Guidelines for Federal Workplace Drug Testing Programs, 53, 69, 11970-11979, 1988.

4. Liu, Ray H. and Goldberger, Bruce A., Handbook of Workplace Drug Testing, AACC Press (1995).

5. Gilman, A. G. and Goodman, L. S., The Pharmacological Basis of Therapeutics, eds. MacMillan Publishing, New York, NY, 1980.

6. Mikkelsen, S.L. et.al., Clin.Chem. 1988; 34: 648

7. Hardman J, Limbird LE (Eds). Goodman & Gilman's The Pharmacological Basis of Therapeutics, 10th Ed., McGraw-Hill Publishing. 2001, 1010.

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DRUGCHECK® Drug Screen Cup

FOR IN VITRO DIAGNOSTIC USE

INTENDED USE

The DrugCheck® Drug Screen Cup is a one-step immunoassay for the qualitative detection of multiple drugs and drug metabolites in human urine at the following cutoff concentrations:

Test	Calibrator	Cutoff (ng/mL)
AMP	Amphetamine	1000
BAR	Secobarbital	300
BUP	Buprenorphine	10
BZO	Oxazepam	300
COC150	Benzoylecgonine	150
COC	Benzoylecgonine	300
MDMA	3,4-methylenedioxymethamphetamine	500
MET500	d-Methamphetamine	500
MET	d-Methamphetamine	1000
MTD	dL-Methadone	300
OPI300	Morphine	300
OPI	Morphine	2000
OXY	Oxycodone	100
PCP	Phencyclidine	25
PPX	Propoxyphene	300
TCA	Nortriptyline	1000
THC	11-nor-Δ9-THC-9 COOH	50

The configurations of the DrugCheck Drug Screen Cup consist of any combination of the drugs listed above. The DrugCheck Drug Screen Cup is used to obtain a visual, qualitative result and is intended for professional use only.

This assay provides only a preliminary result. Clinical consideration and professional judgment must be applied to any drug of abuse test result, particularly in evaluating a preliminary positive result. In order to obtain a confirmed analytical result, a more specific alternate chemical method is needed. Gas Chromatography/Mass Spectroscopy (GC/MS) is the preferred confirmation method.

SUMMARY AND EXPLANATION

Amphetamine/Methamphetamine and their metabolites are potent central nervous system stimulants. Acute doses induce euphoria, alertness, and sense of increased energy and power. Responses from chronic use can include anxiety, paranoia, psychotic behavior, and cardiac dysrhythmias. Methamphetamine and amphetamine are excreted in urine as unchanged drug along with deaminated and hydroxylated derivatives. Methamphetamine also metabolizes to amphetamine in the body. As a result, urine specimens from most methamphetamine users contain both unchanged parent drug and the amphetamine metabolite.

Barbiturates are classified as central nervous system depressants. These products produce a state of intoxication that is similar to alcohol intoxication. Symptoms include slurred speech, loss of motor coordination and impaired judgment. Depending on the dose, frequency, and duration of use, one can rapidly develop tolerance, physical dependence and psychological dependence on barbiturates. Barbiturates are taken orally, or by intravenous and intramuscular injections. Members of the barbiturate drug class typically excrete in urine as parent compound and metabolites.

Benzodiazepines are central nervous system (CNS) depressants commonly prescribed for the short-term treatment of anxiety and insomnia. In general, benzodiazepines act as hypnotics in high doses, as anxiolytics in moderate doses and as sedatives in low doses. The use of benzodiazepines can result in drowsiness and confusion. Psychological and physical dependence on benzodiazepines can develop if high doses of the drug are given over a prolonged period. Benzodiazepines are taken orally or by intramuscular or intravenous injection, and are extensively oxidized in the liver to metabolites. Most benzodiazepines are excreted in the urine as conjugates and metabolites.

Buprenorphine is a synthetic thebaine derivative that has both analgesic and opioid antagonist properties. As an analgesic, it is about 25 to 40 times more potent than morphine. Symptoms of overdosage include confusion, dizziness, pinpoint pupils, hallucinations, hypotension, respiratory difficulty, seizures and coma. Buprenorphine is metabolized in man primarily by N-dealkylation and conjugation to form norbuprenorphine (which is pharmacologically active), and conjugates of Buprenorphine and norbuprenorphine. Within 144 hours of a single intramuscular dose of drug, 95% is eliminated as unchanged drug and the various conjugates and metabolites, with 68% in the feces and 27% in the urine.

Cocaine is a potent central nervous system stimulant and a local anesthetic found in the leaves of the coca plant. The psychological effects induced by using cocaine are euphoria, confidence and sense of increased energy. These psychological effects are accompanied by increased heart rate, dilation of the pupils, fever, tremors and sweating. Cocaine is excreted in the urine primarily as benzoylecgonine in a short period of time.

Benzoylecgonine has a biological half-life of 5 to 8 hours, which is much longer than that of cocaine (0.5 to 1.5 hour), and can be generally detected for 24 to 60 hours after cocaine use or exposure.

3,4-methylenedioxymethamphetamine (MDMA) is classified as both a stimulant and a hallucinogen. Like methamphetamine, adverse effects of 3,4-methylenedioxymethamphetamine use include jaw clenching, teeth grinding, dilated pupils, perspiring, anxiety, blurred vision, vomiting, and increased blood pressure and heart rate. Overdose of 3,4-methylenedioxymethamphetamine may cause heart failure or extreme heat stroke. 3,4-methylenedioxymethamphetamine is taken orally in tablets or capsules and is excreted in urine as parent compound metabolites including methylenedioxyamphetamine (MDA).

Methadone is a synthetic analgesic drug originally used for the treatment of narcotic addiction and pain management. The psychological effects induced by using methadone are analgesia, sedation, and respiratory depression. Overdose of methadone may cause coma or even death. Methadone is taken orally or intravenously and is metabolized in the liver and has a biological half-life of 15-60 hours.

Opiates, such as heroin, morphine, and codeine, are central nervous system (CNS) depressants. The use of opiates at high doses produces euphoria and release from anxiety. Physical dependence is apparent in users and leads to depressed coordination, disrupted decision making, decreased respiration, hypothermia and coma. Heroin is quickly metabolized to 6-acetylmorphine (6-AM), morphine, and morphine glucuronide. Thus, the presence of morphine glucuronide in the urine can indicate heroin, morphine, and/or codeine use.

Oxycodone is a semi-synthetic opioid with a structural similarity to codeine. It produces potent euphoria, analgesic and sedative effects, and has a dependence liability similar to morphine. Oxycodone is most often administered orally and is metabolized by demethylation to noroxycodone and oxymorphone followed by glucuronidation The window of detection for oxycodone in urine is expected to be similar to that of other opioids such as morphine.

Phencyclidine, commonly known as "angel dust" and "crystal cyclone", is an arylcyclohexylamine that is originally used as an anesthetic agent and a veterinary tranquilizer. The drug is abused by oral or nasal ingestion, smoking, or intravenous injection. It produces hallucinations, lethargy, disorientation, loss of coordination, trance-like ecstatic states, a sense of euphoria and visual distortions. It is well absorbed following all routes of administration. Unchanged PCP is excreted in urine in moderate amounts (10% of the dose).

Propoxyphene is a mildly effective narcotic analgesic that has been in clinical use since the 1950s. It is less potent than codeine and bears a close structural relationship to methadone. Propoxyphene is available in oral formulations either as the hydrochloride or as the napsylate salt, and is often dosed in combination with aspirin or acetaminophen. Overdosage of propoxyphene can result in stupor, coma, convulsions, respiratory depression, cardiac arrhythmias, hypotension, pulmonary edema and circulatory collapse. Propoxyphene is metabolized primarily via N-demethylation to norpropoxyphene. The amounts of metabolites excreted in the 20 hour urine following a 130 mg single oral dose of propoxyphene hydrochloride were: 1.1% propoxyphene, 13.2% norpropoxyphene and 0.7% dinorpropoxyphene.

Tetrahydrocannabinol (THC) is generally accepted to be the principle active component in marijuana. When ingested or smoked, it produces euphoric effects. Abusers exhibit central nervous system effects, altered mood and sensory perceptions, loss of coordination, impaired short term memory, anxiety, paranoia, depression, confusion, hallucinations and increased heart rate. When marijuana is ingested, the drug is metabolized by the liver, the primary metabolite of marijuana excreted in the urine is 11-nor-Δ-9-tetrahydrocannabinol-9-carboxylic acid. Therefore, the presence of detected cannabinoids, including the primary carboxyl metabolite, in the urine indicates marijuana/cannabis use.

Tricyclic antidepressants (TCAs) have been prescribed for depression and compulsive disorders. Because of the possibility of causing serious cardiac complications, TCAs can be lethal if misused at high doses. TCAs are taken orally or sometimes by injection. TCAs are metabolized in the liver. Both TCAs and their metabolites are excreted in urine mostly in the form of metabolites for up to ten days.

The length of time following drug use of which a positive result may occur is dependent upon several factors, including the frequency and amount of drug, metabolic rate, excretion rate, drug half-life, and the drug user's age, weight, activity and diet.

TEST PRINCIPLE

The DrugCheck Drug Screen Cup is based on the principle of competitive immunochemical reaction between a chemically labeled drug (drug-protein conjugate) and the drug or drug metabolites which may be present in the urine sample for the limited antibody binding sites. The test contains a nitrocellulose membrane strip pre-coated with drug-protein conjugate

in the test region and a pad containing colored antibody-colloidal gold conjugate. During the test, the urine sample is allowed to migrate upward and rehydrate the antibody-colloidal gold conjugate. The mixture then migrates along the membrane chromatographically by the capillary action to the immobilized drug-protein band on the test region. When drug is absent in the urine, the colored antibody-colloidal gold conjugate and immobilized drug-protein bind specifically to form a visible line in the test region as the antibody complexes with the drug-protein. When drug is present in the urine, it will compete with drug-protein for the limited antibody sites. The line on the test region will become less intense with increasing drug concentration. When a sufficient concentration of drug is present in the urine, it will fill the limited antibody binding sites. This will prevent attachment of the colored antibody-colloidal gold conjugate to the drug-protein on the test region. Therefore, the presence of the line on the test region indicates a negative result for the drug and the absence of a line on the test region indicates a positive result for the drug.

A visible line generated by a different antigen/antibody reaction is also present at the control region of the test strip. This line should always appear, regardless of the presence of drugs or metabolites in the urine sample. This means that a negative urine sample will produce both a test line and control line, and a positive urine sample will generate only a control line. The presence of control line serves as a built-in control, which demonstrates that the test has performed properly.

REAGENTS & MATERIALS SUPPLIED

· 25 individually wrapped test devices. Each device consists of a specimen collection cup and drug test strips in a test strip holder. The test strip contains a colloidal gold pad coated with antibody and rabbit antibody. It also contains a membrane coated with drug-bovine protein conjugate in the test band and goat anti-rabbit antibody in the control band. For the device with adulteration test, an adulteration test strip is also included in each device.

* One instruction sheet
* Security seals (if applicable)
* Adulteration color chart (if applicable)

MATERIAL REQUIRED BUT NOT PROVIDED

· Timer
· Specimen collection container
· External positive and negative controls

WARNINGS AND PRECAUTIONS

· For professional in vitro diagnostic use only.

* Urine specimens may be potentially infectious. Proper handling and disposal methods should be established.

* Avoid cross-contamination of urine samples by using a new specimen collection container for each urine sample.

* Test device should remain sealed until ready for use.

* Do not use the test kit after the expiration date.

* A positive test result does not always mean an individual has taken the drug illegally as the drug can be administered legally.

STORAGE

The DrugCheck Drug Screen Cup should be stored at 2-30°C (36-86°F) in the original sealed pouch. Do not freeze. Do not store and/or expose reagent kits to temperatures greater than 30°C.

SPECIMEN COLLECTION AND HANDLING

Fresh urine does not require any special handling or pretreatment. A fresh urine sample should be collected in the container provided. Alternately, a clean, dry plastic or glass container may be used for specimen collection. If the specimen is not tested immediately it may be refrigerated at 2-8°C up to 2 days or frozen at -20°C for a longer period of time. Specimens that have been refrigerated must be equilibrated to room temperature prior to testing. Specimens previously frozen must be thawed and mixed thoroughly prior to testing.

Note: Urine specimens and all materials coming in contact with them should be handled and disposed as if capable of transmitting infection. Avoid contact with skin by wearing gloves and proper laboratory attire.

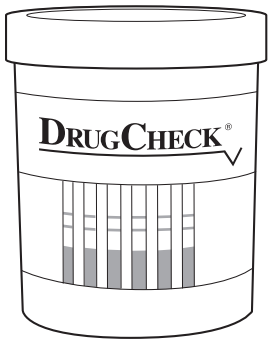
ASSAY PROCEDURE FOR DRUG TEST

Preparation

1. If specimen, control, or test devices have been stored at refrigerated temperatures, allow them to warm to room temperature before testing.
2. Do not open test device pouch until ready to perform the test.

Testing

1. Remove the test cup from the sealed pouch and write donor name or ID on the cup in the section provided.
2. Hand the cup to the individual being tested.
3. Collect the urine into the cup. Ensure the specimen is above the minimum level. A minimum of 30 mL is recommended.
4. Secure test device to the filled specimen cup.
5. Cup must be returned immediately to the collector.
6. Authorized personnel at collection site to remove the tear-off label.
7. Read results of the drugs of abuse tests at 5 minutes. Do not interpret results after 10 minutes.



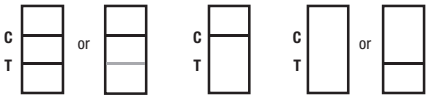
DrugCheck Drug Screen Cup

INTERPRETATION OF RESULTS

Negative (-): Colored lines appear in both control region (C) and test region (T). The line in the control region is the control line, which is used to indicate proper performance of the device. The line in the test region is the drug test line. The test line may have varying intensity either weaker or stronger in color than that of the control line. A negative result for a drug indicates that the concentration of that drug in urine is below the cutoff level.

Positive (+): Colored line appears in the control region. No line appears in the test region. The complete absence of a test line indicates a preliminary positive result for that drug. A preliminary positive result for a drug indicates that the concentration of that drug in urine is at or above the cutoff level.

Invalid: No colored line appears in the control region. If the control line does not form, the test result is invalid and should be repeated.



NEGATIVE (-) POSITIVE (+) INVALID

QUALITY CONTROL

An internal procedural control is included in the test device. A line must form in the control band region regardless of the presence or absence of drugs or metabolites. The presence of the line in the control region indicates that sufficient sample volume has been used and that the reagents are migrating properly. If the line in the control region does not form, the test is considered invalid and must be repeated.

To ensure proper kit performance, it is recommended that the DrugCheck Drug Screen Cup device be tested using external controls with each new lot of product and each new shipment. External controls are available from commercial sources. Additional testing may be necessary to comply with the requirements accrediting organizations and/or local, state, and/or federal regulators.

LIMITATIONS OF PROCEDURE

· The assay is designed for use with human urine only.

* A positive result with any of the tests indicates only the presence of a drug/metabolite and does not indicate or measure intoxication.

* There is a possibility that technical or procedural error as well as other substances or factors not listed may interfere with the test and cause false results. See SPECIFICITY for lists of substances that will produce positive results, or that do not interfere with test performance.

* If adulteration is suspected, the test should be repeated with new a sample.

PERFORMANCE CHARACTERISTICS

A. Accuracy

The accuracy of the DrugCheck Drug Screen Cup was evaluated in comparison to commercially available drug screen tests. Sixty (60) negative urine samples collected from presumed non-user volunteers were tested by both DrugCheck Drug Screen Cup and commercially available drug screen tests. Of these negative urine samples tested, all were found negatives by both methods. In a separate study, positive urine samples, obtained from clinical laboratories where the drug concentrations were determined by GC/MS (TCA concentrations were determined by HPLC), were tested by DrugCheck Drug Screen Cup and commercial drug screen tests. The results of the accuracy study are presented below:

Drug Test		GC/MS (<-50% C/O)	GC/MS (–50% C/O to C/O)	GC/MS (C/O to +50% C/O)	GC/MS (> +50% C/O)	% Agreement with GC/MS
AMP	(+)	0	0	10	55	98.5
	(-)	15	9	1	0	100
BAR	(+)	0	1	5	83	97.8
	(-)	15	7	2	0	95.7
BUP	(+)	0	0	8	35	97.7
	(-)	18	6	1	0	100
BZO	(+)	0	2	13	37	100
	(-)	18	18	0	0	94.7
COC150	(+)	0	1	7	60	100
	(-)	15	10	0	0	96.2
COC300	(+)	0	0	8	71	98.8
	(-)	15	8	1	0	100
MDMA	(+)	0	1	6	37	100
	(-)	24	6	0	0	96.8
MET500	(+)	0	2	8	64	100
	(-)	15	4	0	0	90.5
MET1000	(+)	0	0	5	58	98.4
	(-)	20	8	1	0	100
MTD	(+)	0	0	6	65	98.6
	(-)	15	5	1	0	100
OPI300	(+)	0	1	6	77	100
	(-)	16	6	0	0	95.7
OPI2000	(+)	0	2	9	45	100
	(-)	15	6	0	0	91.3
OXY	(+)	0	2	6	47	100
	(-)	15	6	0	0	91.3
PCP	(+)	0	0	4	56	96.8
	(-)	15	4	2	0	100
PPX	(+)	0	0	6	64	98.6
	(-)	10	7	1	0	100
TCA	(+)	0	1	12	9	100
	(-)	23	11	0	0	97.1
THC	(+)	0	1	24	32	100
	(-)	15	12	0	0	96.4

B.Precision

A study was conducted at three physician offices and the strip manufacturer in an effort to determine the precision of the DrugCheck Drug Screen Cup across three (3) consecutive days. Testing was conducted on the Amphetamine, Barbiturates, Benzodiazepines, Buprenorphine, Cocaine (300 and 150 assays), Marijuana, Methamphetamine (1000 and 500 assays), Methylenedioxymethamphetamine, Methadone, Opiates (2000 and 300 assays), Oxycodone, Phencyclidine, Propoxyphene, and Tricyclic Antidepressants assays using three different lots of product to demonstrate the within-run, between-run and between-operator precision. An identical panel of coded samples, containing drugs at specific concentrations around each assay cutoff was blinded and tested at each site. The correlation with expected results for the solutions targeted to +/- 50% of the cutoff was >99% across all lots, all sites and all operators.

C. Specificity

The specificity for the DrugCheck Drug Screen Cup was determined by testing various drugs, drug metabolites, and other compounds that are likely to be present in urine. All compounds were prepared in drug-free normal human urine.

The following compounds produce positive results when tested at levels greater than the concentrations listed below.

Compound	Conc. (ng/mL)	Compound	Conc. (ng/mL)
Amphetamine			
d-Amphetamine	1,000	d-Methamphetamine	50,000
dL-Amphetamine	2,500	(+/-)3,4-MDMA	50,000
(+/-)3,4-MDA	1,250		
Barbiturates			
Secobarbital	300	Butabarbital	400
Allobarbital	600	Butalbital	300
Alphenal	200	Butethal	450
Amobarbital	1500	Pentobarbital	400
Aprobarbital	300	Phenobarbital	450
Barbital	1500		
Benzodiazepines			
Oxazepam	300	Flunitrazepam	300
Alprazolam	400	Flurazepam	300
Bromazepam	250	Lorazepam	500
Chlordiazepoxide	300	Medazepam	300
Clobazam	1000	Nitrazepam	250
Clonazepam	500	Nordiazepam	150
Clorazepate	150	Prazepam	500
Desalkylflurazepam	200	Temazepam	200
Diazepam	450	Triazolam	450
Estazolam	300		
Buprenorphine			
Buprenorphine	10	Buprenorphine-3-beta-D-glucuronide	7.5
Norbuprenorphine	2500	Norbuprenorphine-3-beta-D-glucuronide	150
Codeine	>100,000		
Morphine	>100,000		
Nalorphine	10,000		
Cocaine Metabolite(150)			
Benzoylecgonine	150	Cocaethylene	>100,000
Cocaine	5,000	Ecgonine methyl esters	>100,000
Ecgonine	>100,000		
Cocaine Metabolite (300)			
Benzoylecgonine	300	Cocaine	300
Methamphetamine (500)			
d-Methamphetamine	500	(+/-)3,4-MDMA	2,000
d-Amphetamine	50,000	l-Methamphetamine	10,000
l-Amphetamine	>100,000	Ephedrine	50,000
(+/-)3,4-MDEA	50,000	Mephentermine	50,000
(+/-)3,4-MDA	100,000		
Methamphetamine (1000)			
d-Methamphetamine	1000	(+/-)3,4-MDMA	3,000
d-Amphetamine	50,000	l-Methamphetamine	10,000
l-Amphetamine	>100,000	Ephedrine	>100,000
(+/-)3,4-MDEA	50,000	Mephentermine	75,000
(+/-)3,4-MDA	100,000		
MDMA			
(+/-)3,4-MDMA	500	(+/-)3,4-MDA	4,000
(+/-)3,4-MDEA	450		
Methadone			
(+/-) Methadone	300	Methadol	1,500
Opiates (300)			
Morphine	300	Hydrocodone	500
Codeine	250	Hydromorphone	500
Ethylmorphine	300	Morphine-3-gluc-uronide	300
Heroin	750	Nalorphine	5,000
Opiates (2000)			
Morphine	2,000	Hydrocodone	4,000
Codeine	2,000	Hydromorphone	5,000
Ethylmorphine	1,000	Morphine-3-gluc-uronide	2,500
Heroin (diacetylmorphine)	5,000	Nalorphine	5,000
Oxycodone			
Oxycodone	100	Morphine	>100,000
Hydrocodone	5000	Codeine	50,000
Hydromorphone	50,000	Nalorphine	5,000
PCP			
Phencyclidine	25	Tenocyclidine	2,000
PPX			
d-Propoxyphine	300	d-Norpropoxyphene	300
THC			
11-nor-D9-THC-9-COOH	50	D9-tetrahydrocan-nabinol	5,000
11-hydroxy-D9-THC	1,000	Cannabinol	10,000

DrugCheck® **Urine Drug Screen**

FOR FORENSIC USE ONLY

INTENDED USE

The DrugCheck® Urine Drug Screen (flat/round cups or dip) is a one-step immunoassay for the qualitative detection of multiple drugs and drug metabolites in human urine at the following cutoff concentrations:

Test	Calibrator	Cut-off (ng/mL)
ALC	Alcohol	0.02 BAC
AMP300	Amphetamine	300
AMP500	Amphetamine	500
AMP1000	Amphetamine	1000
BAR	Secobarbital	300
BUP5	Buprenorphine	5
BUP10	Buprenorphine	10
BZO200	Oxazepam	200
BZO300	Oxazepam	300
COC100	Benzoylecgonine	100
COC150	Benzoylecgonine	150
COC300	Benzoylecgonine	300
COT	(-)-Cotinine	200
EDDP	EDDP	100
EtG	Ethyl Glucuronide	500
FYL	Fentanyl	10
K2-Spice	JW-018; JW-073	50
KET	Ketamine	1000
MDMA	3,4-methylenedioxymethamphetamine	500
MET300	d-Methamphetamine	300
MET500	d-Methamphetamine	500
MET1000	d-Methamphetamine	1000
MTD	dL-Methadone	300
OPI100	Morphine	100
OPI300	Morphine	300
OPI2000	Morphine	2000
OXY	Oxycodone	100
PCP	Phencyclidine	25
PPX	Propoxyphene	300
TCA	Nortriptyline	1000
THC25	11-nor-Δ9-THC-9 COOH	25
THC50	11-nor-Δ9-THC-9 COOH	50
TML	Cis-Tramadol	200

The configurations of the Urine Drug Screen (cup or dip – hereafter "Urine Drug Screen") consist of any combination of the drugs, listed above. The Urine Drug Screen is used to obtain a visual, qualitative result and is intended for professional use only.

This assay provides only a preliminary result. Clinical consideration and professional judgment must be applied to any drug of abuse test result, particularly in evaluating a preliminary positive result. In order to obtain a confirmed analytical result, a more specific alternate chemical method is needed. Gas Chromatography/Mass Spectroscopy (GC/MS) is the preferred confirmation method.

SUMMARY AND EXPLANATION

Alcohol (ALC) Ethyl alcohol, or ethanol, is an intoxicating ingredient found in beer, wine, and liquor. Alcohol is produced by the fermentation of sugars and starches by yeast. Alcohol affects every organ in the body. It is a central nervous system depressant that is rapidly absorbed from the stomach and small intestine into the bloodstream. Alcohol is metabolized in the liver by enzymes, however, the liver can only metabolize a small amount of alcohol at a time, leaving the excess alcohol to circulate throughout the body. The intensity of the effect of alcohol on the body is directly related to the amount consumed.

Amphetamine/Methamphetamine (AMP/MET) and their metabolites are potent central nervous system stimulants. Acute doses induce euphoria, alertness, and sense of increased energy and power. Responses from chronic use can include anxiety, paranoia, psychotic behavior, and cardiac dysrhythmias. Methamphetamine and amphetamine are excreted in urine as unchanged drug along with deaminated and hydroxylated derivatives. Methamphetamine also metabolize to amphetamine in the body. As a result, urine specimens from most methamphetamine users contain both unchanged parent drug and the amphetamine metabolite.

Barbiturates (BAR) are classified as central nervous system depressants. These products produce a state of intoxication that is similar to alcohol intoxication. Symptoms include slurred speech, loss of motor coordination and impaired judgment. Depending on the dose, frequency, and duration of use, one can rapidly develop tolerance, physical dependence and psychological dependence on barbiturates. Barbiturates are taken orally, or by intravenous and intramuscular injections. Members of the barbiturate drug class typically excrete in urine as parent compound and metabolites.

Benzodiazepines (BZO) are central nervous system (CNS) depressants commonly prescribed for the short-term treatment of anxiety and insomnia. In general, benzodiazepines act as hypnotics in high doses, as anxiolytics in moderate doses and as sedatives in low doses. The use of benzodiazepines can result in drowsiness and confusion. Psychological and physical dependence on benzodiazepines can develop if high doses of the drug are given over a prolonged period. Benzodiazepines are taken orally or by intramuscular or intravenous injection, and are extensively oxidized in the liver to metabolites. Most benzodiazepines are excreted in the urine as conjugates and metabolites.

Buprenorphine (BUP) is a synthetic thebaine derivative that has both analgesic and opioid antagonist properties. As an analgesic, it is about 25 to 40 times more potent than morphine. Symptoms of overdosage include confusion, dizziness, pinpoint pupils, hallucinations, hypotension, respiratory difficulty, seizures and coma. Buprenorphine is metabolized in man primarily by N-dealkylation and conjugation to form norbuprenorphine (which is pharmacologically active), and conjugates of Buprenorphine and norbuprenorphine. Within 144 hours of a single intramuscular dose of drug, 95% is eliminated as unchanged drug and the various conjugates and metabolites, with 68% in the feces and 27% in the urine.

Cocaine (COC) is a potent central nervous system stimulant and a local anesthetic found in the leaves of the coca plant. The psychological effects induced by using cocaine are euphoria, confidence and sense of increased energy. These psychological effects are accompanied by increased heart rate, dilation of the pupils, fever, tremors and sweating. Cocaine is excreted in the urine primarily as benzoylecgonine in a short period of time. Benzoylecgonine has a biological half-life of 5 to 8 hours, which is much longer than that of cocaine (0.5 to 1.5 hour), and can be generally detected for 24 to 60 hours after cocaine use or exposure.

Cotinine (COT) is the first-stage metabolite of nicotine, a toxic alkaloid that produces stimulation of the autonomic ganglia and central nervous system when in humans. Nicotine is a drug to which virtually every member of a tobacco-smoking society is exposed whether through direct contact or second-hand inhalation. In addition to tobacco, nicotine is also commercially available as the active ingredient in smoking replacement therapies such as nicotine gum, transdermal patches and nasal sprays. In a 24-hour urine, approximately 5% of a nicotine dose is excreted as unchanged drug with 10% as cotinine and 35% as hydroxycotinine; the concentrations of other metabolites are believed to account for less than 5%. While cotinine is

thought to be an inactive metabolite, it's elimination profile is more stable than that of nicotine which is largely urine pH dependent. As a result, cotinine is considered a good biological marker for determining nicotine use. The plasma half-life of nicotine is approximately 60 minutes following inhalation or parenteral administration. Nicotine and cotinine are rapidly eliminated by the kidney; the window of detection for cotinine in urine at a cutoff level of 200 ng/mL is expected to be up to 2-3 days after nicotine use.

EDDP 2-Ethylidine-1,5-dimethyl-3,3-diphenylpyrrolidine, is the primary metabolite of methadone. Methadone is a controlled substance and is used for detoxification and maintenance of opiate dependant patients. Patients on methadone maintenance may exhibit methadone (parent) levels that account for 5-50% of the dosage and 3-25% of EDDP in urinary excretion during the first 24 hours. The detection of EDDP is more beneficial than traditional methadone screening, in that EDDP exists only in urine from individuals that ingested methadone. The tampering of specimens by spiking the urine with methadone can be prevented. Secondly, renal clearance of EDDP is not affected by urinary pH, therefore the EDDP test provides a more accurate result of methadone ingestion than the methadone parent screen.

EtG Ethyl Glucuronide (EtG) is a direct metabolite of ethanol, which is formed by enzymatic conjugation of ethanol with glucuronic acid. Alcohol in urine is normally detected for only a few hours, whereas EtG can be detected up to several days even after complete elimination of alcohol from the body. Therefore, EtG can be a useful diagnostic biomarker for determining recent alcohol use and in monitoring abstinence in alcoholics in alcohol withdrawal treatment programs.

Fentanyl (FYL) is a synthetic opioid related to the phenylpiperidines. Fentanyl is approximately 100 times more potent than morphine. This agent is highly lipid soluble and rapidly cross the blood-brain barrier. This is reflected in the half-life for equilibration between the plasma and cerebrospinal fluid of approximately 5 minutes for fentanyl. The levels in plasma and cerebrospinal fluid decline rapidly owing to redistribution of fentanyl from highly perfused tissue groups to other tissues, such as muscle and fat. As saturation of less well-perfused tissue occurs, the duration of effect of fentanyl and sufentanil approaches the length of their elimination half-lives of between 3 and 4 hours. Fentanyl undergoes hepatic metabolism and renal excretion. Therefore, with the use of higher doses or prolonged infusions, fentanyl becomes longer acting.

Ketamine (KET), most commonly known today as a party drug, is abused by many teenagers and young adults. Ketamine is a chiral compound. It is a white, crystalline powder or clear liquid. It has been used in clinical for more than 30 years and still used in human medicine as an anaesthetic. Sometimes used in anesthesia for emergency surgery and for the treatment of alcoholism and heroin addiction. Low dose intoxication results in impaired attention learning and memory function. High dose may cause anxiety, chest pain, agitation, delirium, psychosis, dizziness, vomiting, seizures and paranoia.

3,4-methylenedioxymethamphetamine (MDMA) is classified as both a stimulant and a hallucinogen. Like methamphetamine, adverse effects of 3,4-methylenedioxymethamphetamine use include jaw clenching, teeth grinding, dilated pupils, perspiring, anxiety, blurred vision, vomiting, and increased blood pressure and heart rate. Overdose of 3,4-methylenedioxymethamphetamine may cause heart failure or extreme heat stroke. 3,4-methylenedioxymethamphetamine is taken orally in tablets or capsules and is excreted in urine as parent compound metabolites including methylenedioxyamphetamine (MDA).

Methadone (MTD) is a synthetic analgesic drug originally used for the treatment of narcotic addiction and pain management. The psychological effects induced by using methadone are analgesia, sedation, and respiratory depression. Overdose of methadone may cause coma or even death. Methadone is taken orally or intravenously and is metabolized in the liver and has a biological half-life of 15-60 hours.

Opiates (OPI), such as heroin, morphine, and codeine, are central nervous system (CNS) depressants. The use of opiates at high doses produces euphoria and release from anxiety. Physical dependence is apparent in users and leads to depressed coordination, disrupted decision making, decreased respiration, hypothermia and coma. Heroin is quickly metabolized to 6-acetylmorphine (6-AM), morphine, and morphine glucuronide. Thus, the presence of morphine glucuronide in the urine can indicate heroin, morphine, and/or codeine use.

Oxycodone (OXY) is a semi-synthetic opioid with a structural similarity to codeine. It produces potent euphoria, analgesic and sedative effects, and has a dependence liability similar to morphine. Oxycodone is most often administered orally and is metabolized by demethylation to noroxycodone and oxymorphone followed by glucuronidation The window of detection for oxycodone in urine is expected to be similar to that of other opioids such as morphine.

Phencyclidine (PCP), commonly known as "angel dust" and "crystal cyclone", is an arylcyclohexylamine that is originally used as an anesthetic agent and a veterinary tranquilizer. The drug is abused by oral or nasal ingestion, smoking, or intravenous injection. It produces hallucinations, lethargy, disorientation, loss of coordination, trance-like ecstatic states, a sense of euphoria and visual distortions. It is well absorbed following all routes of administration. Unchanged PCP is excreted in urine in moderate amounts (10% of the dose).

Propoxyphene (PPX) is a mildly effective narcotic analgesic that has been in clinical use since the 1950s. It is less potent than codeine and bears a close structural relationship to methadone. Propoxyphene is available in oral formulations either as the hydrochloride or as the napsylate salt, and is often dosed in combination with aspirin or acetaminophen. Overdosage of propoxyphene can result in stupor, coma, convulsions, respiratory depression, cardiac arrhythmias, hypotension, pulmonary edema and circulatory collapse. Propoxyphene is metabolized primarily via N-demethylation to norpropoxyphene. The amounts of metabolites excreted in the 20 hour urine following a 130 mg single oral dose of propoxyphene hydrochloride were: 1.1% propoxyphene, 13.2% norpropoxyphene and 0.7% dinorpropoxyphene.

Tetrahydrocannabinol (THC) is generally accepted to be the principle active component in marijuana. When ingested or smoked, it produces euphoric effects. Abusers exhibit central nervous system effects, altered mood and sensory perceptions, loss of coordination, impaired short term memory, anxiety, paranoia, depression, confusion, hallucinations and increased heart rate. When marijuana is ingested, the drug is metabolized by the liver, the primary metabolite of marijuana excreted in the urine is 11-nor-□-9-tetrahydrocannabinol-9-carboxylic acid. Therefore, the presence of detected cannabinoids, including the primary carboxyl metabolite, in the urine indicates marijuana/cannabis use.

Tricyclic antidepressants (TCA) have been prescribed for depression and compulsive disorders. Because of the possibility of causing serious cardiac complications, TCAs can be lethal if misused at high doses. TCAs are taken orally or sometimes by injection. TCAs are metabolized in the liver. Both TCAs and their metabolites are excreted in urine mostly in the form of metabolites for up to 10 days.

Tramadol (TML) is a quasi-narcotic analgesic used in the treatment of moderate to severe pain. It is a synthetic analog of codeine, but has a low binding affinity to the mu-opioid receptors. Large doses of tramadol can develop tolerance and physiological dependency and lead to its abuse. Tramadol is extensively metabolized after oral administration. Approximately 30% of the dose is excreted in the urine as unchanged drug, whereas 60% is excreted as metabolites. The major pathways appear to be N- and O-demethylation, glucoronidation or sulfation in the liver.

The length of time following drug use of which a positive result may occur is dependent upon several factors, including the frequency and amount of drug, metabolic rate, excretion rate, drug half-life, and the drug user's age, weight, activity and diet.

TEST PRINCIPLE

The Urine Drug Screen is based on the principle of competitive immunochemical reaction between a chemically labeled drug (drug-protein conjugate) and the drug or drug metabolites which may be present in the urine sample for the limited antibody binding sites. The test contains a nitrocellulose membrane strip pre-coated with drug-protein conjugate in the test region and a pad containing colored antibody-colloidal gold conjugate. During the test, the urine sample is allowed to migrate upward and rehydrate the antibody-colloidal gold conjugate. The mixture then migrates along the membrane chromatographically by the capillary action to the immobilized drug-protein band on the test region. When drug is absent in the urine, the colored antibody-colloidal gold conjugate and immobilized drug-protein bind specifically to form a visible line in the test region as the antibody complexes with the drug-protein. When drug is present in the urine, it will compete with drug-protein for the limited antibody sites. The line on the test region will become less intense with increasing drug concentration. When a sufficient concentration of drug is present in the urine, it will fill the limited antibody binding sites. This will prevent attachment of the colored antibody-colloidal gold conjugate to the drug-protein on the test region. Therefore, the presence of the line on the test region indicates a negative result for the drug and the absence of a line on the test region indicates a positive result for the drug.

A visible line generated by a different antigen/antibody reaction is also present at the control region of the test strip. This line should always appear, regardless of the presence of drugs or metabolites in the urine sample. This means that a negative urine sample will produce both a test line and control line, and a positive urine sample will generate only a control line. The presence of control line serves as a built-in control, which demonstrates that the test is performed properly.

REAGENTS & MATERIALS SUPPLIED

· Individually wrapped test devices. Each device consists of a specimen collection cup and drug test strip(s) in a test strip holder. Each test line contains anti-drug mouse monoclonal antibody and corresponding drug-protein conjugates. The control line contains goat anti-rabbit IgG polyclonal antibodies and rabbit IgG.
For devices with adulteration or alcohol tests, the corresponding test strip is also included.

· One product insert · Security seals (if applicable)

· Adulteration, urine alcohol color chart (if applicable)

MATERIAL REQUIRED BUT NOT PROVIDED

·Timer · Specimen collection container (dip only)
· External positive and negative controls

WARNINGS AND PRECAUTIONS

· For IVD use only.
· Urine specimens may be potentially infectious. Proper handling and disposal methods should be established.
· Avoid cross-contamination of urine samples by using a new specimen collection container for each urine sample.
· Test device should remain sealed until ready for use.
· Do not use the test kit after the expiration date.
· A positive test result does not always mean an individual has taken the drug illegally, as some drugs can be administered legally.

STORAGE

The Urine Drug Screen should be stored at 2-30°C (36-86°F) in the original sealed pouch. Do not freeze. Do not store and/or expose reagent kits to a temperature greater than 30°C. Product containing K2/Spice test strips should be stored at 4-30°C (39-86°F).

SPECIMEN COLLECTION AND HANDLING

Fresh urine does not require any special handling or pretreatment. A fresh urine sample should be collected in the Urine Drug Screen, or in a plastic or glass container for the dip test. Alternately, a clean, dry plastic or glass container may be used for specimen collection. If the specimen will not be tested immediately after collection, it may be refrigerated at 2-8°C up to two days or frozen at -20°C for a longer period of time. Specimens that have been refrigerated must be equilibrated to room temperature prior to testing. Specimens previously frozen must be thawed and mixed thoroughly prior to testing.

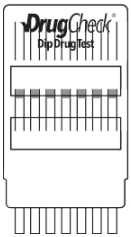
Note: Urine specimens and all materials coming in contact with them should be handled and disposed as if capable of transmitting infection. Avoid contact with skin by wearing gloves and proper laboratory attire.

ASSAY PROCEDURE FOR URINE DRUG SCREENS

For Drug Screen Cup

1. Bring all materials and specimens to room temperature.
2. Remove the test cup from the sealed pouch.
3. Issue the cup to the individual to be tested.
4. Collect urine into the cup. Ensure specimen is above the minimum level.
5. The cup must be returned immediately to the collector. Authorized personnel should remove the tear-off label.
6. Read results of drugs of abuse tests in 5 minutes. Do not interpret result after 10 minutes.

For Dip Drug Test



1. Bring all materials and specimens to room temperature.
2. Issue a collection cup to the individual to be tested.
3. Collect the urine into the cup.
4. Remove test card from sealed pouch and remove cap from sampling tips.
5. Immerse sampling tips into the urine specimen for 15 seconds and then place the test on a flat surface with the cap on.
6. Read results of drugs of abuse tests in 5 minutes. Do not interpret result after 10 minutes.

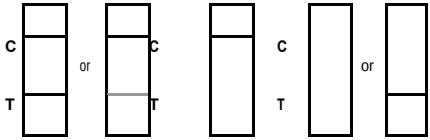
INTERPRETATION OF RESULTS

Negative (-): Colored lines appear in both control region (C) and test region (T). The line in the control region is the control line, which is used to indicate proper performance of the device. The line in the test region is the drug probe line. The test line may have varying intensity either weaker or stronger in color than that of the control line. A negative result for a drug indicates that the concentration of that drug in urine is below the cutoff level.

Positive (+): Colored line appears in the control region. No line appears in the test region. The complete absence of a test line indicates a preliminary positive result for that drug. A preliminary positive result for a drug indicates that the

concentration of that drug in urine is at or above the cutoff level.

Invalid: No colored line appears in the control region. If the control line does not form, the test result is inconclusive and should be repeated.



NEGATIVE (-) POSITIVE (+) INVALID

Note: A borderline (+/-) in test line zone should be considered a negative result.

QUALITY CONTROL

An internal procedural control is included in the test device. A line must form in the control band (C) region regardless of the presence or absence of drugs or metabolites. The presence of the line in the control region indicates that sufficient sample volume has been used and that the reagents are migrating properly. If the line in the control region does not form, the test is considered invalid and must be repeated.

To ensure proper kit performance, it is recommended that the Urine Drug Screen device be tested using external controls with each new lot of product and each new shipment. External controls are available from commercial sources. Additional testing may be necessary to comply with the requirements of accrediting organizations and/or local, state, and/or federal regulators.

LIMITATIONS OF PROCEDURE

· The assay is designed for use with human urine only.
· A positive result with any of the tests indicates only the presence of a drug/metabolite and does not indicate or measure intoxication.
· There is a possibility that technical or procedural error as well as other substances or factors not listed may interfere with the test and cause false results. See SPECIFICITY for lists of substances that will produce positive results, or that do not interfere with test performance.
· If adulteration is suspected, the test should be repeated with a new sample and device.

PERFORMANCE CHARACTERISTICS

A. Accuracy

A side-by-side comparison was conducted using Urine Drug Screen and commercially available drug rapid tests. Testing was performed on approximately 250 specimens per drug type previously collected from subjects presenting for Drug Screen Testing. Presumptive positive results were confirmed by GC/MS. The results of the accuracy study follow:

Test		GC/MS		Accuracy
		Positive	Negative	
AMP 300	Positive	116	2	99.1%
	Negative	1	131	98.5%
AMP 500	Positive	110	2	99.1%
	Negative	1	137	98.6%
AMP 1,000	Positive	103	3	98.1%
	Negative	2	142	97.9%
BAR 300	Positive	98	2	96.1%
	Negative	4	146	98.6%
BUP 5	Positive	105	0	99.1%
	Negative	1	144	>99.9%
BUP 10	Positive	105	0	99.1%
	Negative	1	144	>99.9%
BZO 200	Positive	127	2	99.2%
	Negative	1	120	98.4%
BZO 300	Positive	121	1	98.4%
	Negative	2	126	99.2%
COC 100	Positive	117	4	99.2%
	Negative	1	128	97.0%
COC 150	Positive	116	4	98.3%
	Negative	2	128	97.0%
COC 300	Positive	111	3	98.2%
	Negative	2	134	97.8%
COT 200	Positive	88	4	96.7%
	Negative	3	155	97.5%
EDDP 100	Positive	95	5	96.9%
	Negative	3	147	96.7%
ETG500	Positive	83	1	97.6%
	Negative	2	164	99.4%
FYL 10	Positive	80	1	98.8%
	Negative	1	168	99.4%
K2-Spice 50	Positive	78	3	97.5%
	Negative	2	167	98.2%
KET 1,000	Positive	77	3	97.5%
	Negative	2	168	98.2%
MDMA 500	Positive	102	1	98.1%
	Negative	2	145	99.3%
MET 300	Positive	88	4	97.8%
	Negative	2	156	97.5%
MET 500	Positive	83	5	97.6%
	Negative	2	160	97.0%
MET 1,000	Positive	76	5	96.2%
	Negative	3	166	97.1%
MTD 300	Positive	89	2	98.9%
	Negative	1	158	98.8%
OPI 100	Positive	98	5	97.0%
	Negative	3	144	96.6%
OPI 300	Positive	95	7	95.0%
	Negative	5	143	95.3%
OPI 2000	Positive	117	8	96.7%
	Negative	4	121	93.8%
OXY 100	Positive	84	1	97.7%
	Negative	2	163	99.4%
PCP 25	Positive	85	5	92.4%
	Negative	7	153	96.8%
PPX 300	Positive	97	9	96.0%
	Negative	4	140	94.0%
TCA	Positive	91	13	94.8%
	Negative	5	141	91.6%
THC 25	Positive	95	4	96.9%
	Negative	3	148	97.4%
THC 50	Positive	92	3	97.9%
	Negative	2	153	98.1%
TML 200	Positive	82	6	88.2%
	Negative	11	151	96.2%

B. Precision

A study was conducted at three hospitals by laypersons in an effort to determine the precision of the product. Testing was performed on the drugs referenced in the Intended Use section of this product insert with assays using three different lots of product to demonstrate the within-run, between-run, and between-operator precision. An identical card of coded samples, containing no drug, drugs at concentrations of ± 50% and ± 25% cut-off level, was labeled, blinded and tested at each site.

Samples determined to be negative, -50% cutoff, -25% cutoff, +25% cutoff and +50% cutoff values demonstrate high precision for all lots, all sites, and all operators.

C. Specificity

The specificity for the Urine Drug Screen was determined by testing various drugs, drug metabolites, and other compounds that are likely to be present in urine. All compounds were prepared in drug-free normal human urine.

The following compounds produced positive results when tested at levels greater than the concentrations listed below.

Analytes	Concentration (ng/mL)	Analytes	Concentration (ng/mL)
AMPHETAMINE (AMP 300)			
D,L-Amphetamine sulfate	75	Phentermine	300
L-Amphetamine	10,000	Maprotiline	15,000
(±) 3,4-Methylenedioxy amphetamine	150	Methoxyphenamine	2,000
		D-Amphetamine	300
AMPHETAMINE (AMP 500)			
D,L-Amphetamine sulfate	150	Phentermine	500
L-Amphetamine	12,500	Maprotiline	25,000
(±) 3,4-Methylenedioxy amphetamine	250	Methoxyphenamine	3,000
		D-Amphetamine	500
AMPHETAMINE (AMP 1,000)			
D,L-Amphetamine sulfate	300	Phentermine	1,000
L-Amphetamine	25,000	Maprotiline	50,000
(±) 3,4-Methylenedioxy amphetamine	500	Methoxyphenamine	6,000
		D-Amphetamine	1,000
BARBITURATES (BAR 300)			
Amobarbital	5,000	Alphenol	600
5,5-Diphenylhydantoin	8,000	Aprobarbital	500
Allobarbital	600	Butabarbital	200
Barbital	8,000	Butalbital	8,000
Talbutal	200	Butethal	500
Cyclopentobarbital	30,000	Phenobarbital	300
Pentobarbital	8,000	Secobarbital	300
BUPRENORPHINE (BUP 5)			
Buprenorphine	5	Norbuprenorphine	25
Buprenorphine 3-D-Glucuronide	25	Norbuprenorphine 3-D-Glucuronide	50
BUPRENORPHINE (BUP 10)			
Buprenorphine	10	Norbuprenorphine	50
Buprenorphine 3-D-Glucuronide	50	Norbuprenorphine 3-D-Glucuronide	100
BENZODIAZEPINES (BZO 200)			
Alprazolam	70	Bromazepam	600
a-hydroxyalprazolam	1,000	Chlordiazepoxide	600
Clobazam	120	Nitrazepam	120
Clonazepam	300	Norchlordiazepoxide	70
Clorazepatedipotassium	300	Nordiazepam	600
Delorazepam	600	Oxazepam	200
Desalkylflurazepam	120	Temazepam	70
Flunitrazepam	120	Diazepam	200
(±) Lorazepam	2,000	Estazolam	4,000
RS-Lorazepamglucuronide	120	Triazolam	2,000
Midazolam	4,000		
BENZODIAZEPINES (BZO 300)			
Alprazolam	100	Bromazepam	900
a-hydroxyalprazolam	1,500	Chlordiazepoxide	900
Clobazam	200	Nitrazepam	200
Clonazepam	500	Norchlordiazepoxide	100
Clorazepatedipotassium	500	Nordiazepam	900
Delorazepam	900	Oxazepam	300
Desalkylflurazepam	200	Temazepam	100
Flunitrazepam	200	Diazepam	300
(±) Lorazepam	3,000	Estazolam	6,000
RS-Lorazepamglucuronide	200	Triazolam	3,000
Midazolam	6,000		
COCAINE (COC 100)			
Benzoylecgonine	100	Cocaethylene	7,000
Cocaine HCl	80	Ecgonine	10,000
COCAINE (COC 150)			
Benzoylecgonine	150	Cocaethylene	1,0000
Cocaine HCl	120	Ecgonine	15,000
COCAINE (COC 300)			
Benzoylecgonine	300	Cocaethylene	20,000
Cocaine HCl	200	Ecgonine	30,000
Cotinine (COT 200)			
(-)-Cotinine	200	(-)-Nicotine	5,000

2-Ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine (EDDP100)			
2-Ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine (EDDP)			100
Ethyl- β-D-Glucuronide(ETG500)			
Ethyl- β -D-Glucuronide	500	Propyl β-D-glucuronide	50,000
Morphine 3β-glucuronide	100,000	Morphine 6β-glucuronide	100,000
Glucuronic Acid	100,000	Ethanol	>100,000
Methanol	>100,000		
Fentanyl (FYL10)			
Alfentanyl	300,000	Buspirone	8,000
Fenfluramine	25,000	Fentanyl	50
Norfentanyl	10	Sufentanyl	25,000
Synthetic Marijuana (K2-Spice 50)			
JWH-018 5-Pentanoic acid	50	JWH-073 4-butanoic acid	50
JWH-018 4-Hydroxypentyl	400	JWH-018 5-Hydroxypentyl	500
JWH-073 4-Hydroxybuty	500		
KETAMINE (KET1, 000)			
Ketamine	1,000	Benzphetamine	25,000
Dextromethorphan	2,000	(+) Chlorpheniramine	25,000
Methoxyphenamine	25,000	Clonidine	100,000
d-Norpropoxyphene	25,000	EDDP	50,000
Promazine	25,000	4-Hydroxyphencyclidine	50,000
Promethazine	25,000	Levorphanol	50,000
Pentazocine	25,000	MDE	50,000
Phencyclidine	25,000	Meperidine	25,000
Tetrahydrozoline	500	d-Methamphetamine	50,000
Mephentermine	25,000	l-Methamphetamine	50,000
(1R, 2S) - (-)-Ephedrine	100,000	3,4-Methylendioxymethamphetamine (MDMA)	100,000
Disopyramide	25,000	Thioridazine	50,000
METHYLENEDIOXYMETHAMPHETAMINE (MDMA500) Ecstasy			
(±) 3,4-Methylenedioxy methamphetamine HCl	500	3,4-Methylenedioxyethyl-amphetamine	300
(±) 3,4-Methylenedioxyampheta mine HCl	3,000		
METHAMPHETAMINE (MET300)			
p-Hydroxymethamphetamine	7,500	(±)-3,4-Methylenedioxy-methamphetamine	3,750
D-Methamphetamine	300		
L-Methamphetamine	6,000	Mephentermine	15,000
METHAMPHETAMINE (MET500)			
p-Hydroxymethamphetamine	12,500	(±)-3,4-Methylenedioxy-methamphetamine	6,250
D-Methamphetamine	500		
L-Methamphetamine	10,000	Mephentermine	25,000
METHAMPHETAMINE (MET1, 000)			
p-Hydroxymethamphetamine	25,000	(±)-3,4-Methylenedioxy-methamphetamine	12,500
D-Methamphetamine	1,000		
L-Methamphetamine	20,000	Mephentermine	50,000
METHADONE (MTD300)			
Methadone	300	Doxylamine	100,000
MORPHINE (OPI 100)			
Codeine	80	Norcodeine	2,000
Levorphanol	500	Normorphone	20,000
Morphine-3-β-D-Glucuronide	300	Oxycodone	10,000
Ethylmorphine	2,000	Oxymorphone	20,000
Hydrocodone	20,000	Procaine	5,000
Hydromorphone	1,000	Thebaine	2,000
6-Monoacethylmorphine	200	Morphine	100
MORPHINE (OPI 300)			
Codeine	200	Norcodeine	6,000
Levorphanol	1,500	Normorphone	50,000
Morphine-3-β-D-Glucuronide	800	Oxycodone	30,000
Ethylmorphine	6,000	Oxymorphone	50,000
Hydrocodone	50,000	Procaine	15,000
Hydromorphone	3,000	Thebaine	6,000
6-Monoacethylmorphine	300	Morphine	300
MORPHINE/OPIATE (OPI 2,000)			
Codeine	2,000	Morphine	2,000
Ethylmorphine	3,000	Norcodeine	25,000

Hydrocodone	50,000	Normorphone	50,000
Hydromorphone	15,000	Oxycodone	25,000
Levorphanol	25,000	Oxymorphone	25,000
6-Monoacetylmorphine	3,000	Procaine	50,000
Morphine 3-β-D-glucuronide	2,000	Thebaine	25,000
Oxycodone (OXY100)			
Oxycodone	100	Hydromorphone	50,000
Oxymorphone	300	Naloxone	25,000
Levorphanol	50,000	Naltrexone	25,000
Hydrocodone	25,000		
PHENCYCLIDINE (PCP)			
Phencyclidine	25	4-Hydroxyphencyclidine	12,500
PROPOXYPHENE (PPX)			
D-Propoxyphene	300	D-Norpropoxyphene	300
TRICYCLIC ANTIDEPRESSANTS (TCA)			
Nortriptyline	1,000	Imipramine	400
Nordoxepine	500	Clomipramine	50,000
Trimipramine	3,000	Doxepine	2,000
Amitriptyline	1,500	Maprotiline	2,000
Promazine	3,000	Promethazine	50,000
Desipramine	200	Perphenazine	50,000
Cyclobenzaprine	2,000	Dithiaden	10,000
MARIJUANA (THC25)			
Cannabinol	17,500	Δ8-THC	8,500
11-nor-Δ8-THC-9 COOH	15	Δ9-THC	8,500
11-nor-Δ9-THC-9 COOH	25		
MARIJUANA (THC50)			
Cannabinol	35,000	Δ8-THC	17,000
11-nor-Δ8-THC-9 COOH	30	Δ9-THC	17,000
11-nor-Δ9-THC-9 COOH	50		
TRAMADOL (TML 200)			
n-Desmethyl-cis-tramadol	400	o-Desmethyl-cis-tramadol	20,000
Cis-tramadol	200	Phencyclidine	200,000
Procyclidine	200,000	d,l-O-Desmethyl venlafaxine	100,000

D. Interference

The following compounds were evaluated for potential positive and/or negative interference with the Urine Drug Screen. All compounds were dissolved in the drug control solutions with 50% below and 50% above cutoff concentrations and tested with the Urine Drug Screen. An unaltered sample was used as a control.

No positive interference or negative interference was found for the following compounds when tested at concentrations up to 100 µg/mL.

Acetophenetidin	Diphenhydramine	Oxolinic acid
N-Acetylprocainamide	Ethyl-p-aminobenzoate	Oxymetazoline
Acetylsalicylic acid	β-Estradiol	Papaverine
Aminopyrine	Estrone-3-sulfate	Penicillin-G
Amoxicillin	Erythromycin	Perphenazine
Ampicillin	Fenoprofen	Phenelzine
l-Ascorbic acid	Furosemide	Prednisone
Apomorphine	Gentisic acid	d,l-Propanolol
Aspartame	Hemoglobin	d-Pseudoephedrine
Atropine	Hydralazine	Quinidine
Benzilic acid	Hydrochlorothiazide	Quinine
Benzoic acid	Hydrocortisone	Salicylic acid
Bilirubin	o-Hydroxyhippuric acid	Serotonin
d,l-Brompheniramine	3-Hydroxytyramine	Sulfamethazine
Caffeine	d,l-Isoproterenol	Sulindac
Cannabidiol	Isoxsuprine	Tetracycline
Chloral hydrate	Ketoprofen	Tetrahydrocortisone, 3-acetate
Chloramphenicol	Labetalol	Tetrahydrocortisone
Chlorothiazide	Loperamide	Tetrahydrozoline
d,l-Chlorpheniramine	Meprobamate	Thiamine
Chlorpromazine	Methoxyphenamine	Thioridazine
Cholesterol	Methylphenidate	d,l-Tyrosine
Clonidine	Nalidixic acid	Tolbutamide
Cortisone	Naproxen	Triamterene
Creatinine	Niacinamide	Trifluoperazine
Deoxycorticosterone	Nifedipine	Trimethoprim
Dextromethorphan	Norethindrone	d,l-Tryptophan
Diclofenac	Noscapine	Uric acid
Diflunisal	d,l-Octopamine	Verapamil
Digoxin	Oxalic acid	Zomepirac

E. Effect of Specimen pH

Drug sample solutions with 50% below and 50% above cutoff concentrations were adjusted to pH 5-9 and tested using the Urine Drug Screen. An unaltered sample was used as a control. The results demonstrate that varying ranges of specimen pH do not interfere with the performance of the test.

F. Effect of Specimen Specific Gravity

Drug sample solutions with 50% below and 50% above cutoff concentrations were adjusted to specific gravity 1.005-1.045 and tested using the Urine Drug Screen. An unaltered sample was used as a control. The results demonstrate that varying ranges of specimen specific gravity do not interfere with the performance of the test.

ADULTERATION TESTS

Adulteration of urine samples may cause erroneous results in drugs of abuse tests by either interfering with the drug screening test and/or destroying the drugs in the urine. Dilution of urine with water is probably the simplest urine adulteration method. Bleach, vinegar, eye drops, sodium bicarbonate, sodium nitrite, Drano, soft drinks and hydrogen peroxide are examples of adulterants used to adulterate urine samples. It is important to insure the integrity of urine samples in drugs of abuse testing.

The Urine Drug Screen with adulteration test is based on the color response of chemical indicators in the presence of adulterants. Creatinine (Cr), nitrite (Ni), pH, bleach/oxidant (Bl), and specific gravity (S.G.) are tested to determine the integrity of urine samples.

Cr: Creatinine reacts with a creatinine indicator in an alkaline medium to form a purplish-brown color complex. The color intensity is directly proportional to the concentration of creatinine. A urine sample with a creatinine concentration of less than 20 mg/dL is indicative of adulteration.

Ni: Nitrite reacts with the reagent's aromatic amine to form a diazonium salt which couples with an indicator to yield a pink-red/purple color complex. A urine sample containing nitrite at a level greater than 15 mg/ dL is considered adulterated.

pH: The pH determination of urine sample is based on the color change of an indicator in an acidic or basic medium. Normal urine pH ranges from 4 to 9. A urine pH below 4 or above 9 indicates adulteration with acid or base to the sample.

Bl: Bleach or other oxidizing agents react with an oxidant indicator to form a color complex. Observation of a blue-green, brown, or orange color indicates adulteration with bleach or other oxidizing agents.

S.G.: The specific gravity test is based on the pKa change of certain pretreated polyelectrolytes in relation to the ionic concentration. In the presence of an indicator, the colors change from dark blue to blue-green in urine of low ionic concentration to green and yellow-green in urine of higher ionic concentration. A urine specific gravity below 1.005 or above 1.025 is considered abnormal.

PERFORMING THE ASSAY WITH ADULTERATION TEST

Preparation

1. If specimen, control, or test devices have been stored at refrigerated temperatures, allow them to warm to room temperature before testing.
2.Do not open test device pouch until ready to perform the test.

Testing (Please refer to the color chart)

Semi-quantitative results are obtained by visually comparing the reacted color blocks on the adulteration strips to the printed color blocks on the color chart. No instrumentation is required.

1. Remove the test cup from the sealed pouch.
2. Hand the cup to the individual being tested.
3. Collect the urine into the cup. A minimum of 30 mL is recommended.
4. Secure the test device cap to the specimen cup. The cup must be returned immediately to the collector.
5. Read the adulteration strips between 3 and 5 minutes. Compare the colors on the adulteration strip to the enclosed color chart. If the specimen indicates adulteration, refer to your Drug Free Policy for guidelines on adulterated specimens. We recommend not to interpret the drug test results and either retest the urine or collect another specimen.
6. Authorized personnel should remove the tear-off label.
7. Read results of the drugs of abuse tests at 5 minutes. Do not interpret results after 10 minutes.

URINE ALCOHOL TEST

INTENDED USE

The Urine Alcohol Test Strip is a rapid, highly sensitive method to detect the presence of alcohol in human urine. This test provides a preliminary result only. A more specific alternate chemical method must be used in order to obtain a confirmed analytical result. Gas Chromatography/Mass Spectrometry (GC/MS) is the preferred confirmatory method. Clinical consideration and professional judgment should be applied to any result, particularly when preliminary positive results are indicated.

PRINCIPLE

The Urine Alcohol Test Strip is a chemical assay based on an alcohol-sensitive enzymatic reaction. Alcohol, if present in the specimen, reacts with chemicals on the reaction pad and causes a color change.

The Urine Alcohol Test Strip consists of a plastic strip with a reaction pad. The reaction pad employs a solid-phase chemistry system which uses a highly specific enzyme reaction. On contact with urine, the reaction pad will rapidly change color depending on the concentration of alcohol present. This color change is proportional to the concentration of alcohol in the specimen. By comparing with the color blocks on the color chart supplied with the kit.

REAGENTS

The test strip contains 1.3%(w/w) 3,3',5,5'-Tetramethylbenzidine, 0.3%(w/w) Alcohol Oxidase, 0.1%(w/w) Peroxidase, 12.6%(w/w) buffer and 85.8% non-reaction additives.

PRECAUTIONS

- For professional in vitro diagnostic use only.
- Do not use after the expiration date.
- All specimens and test materials that have been exposed to the specimen should be treated as potentially infectious.
- Follow proper precautions and local regulations when disposing of the test.
- The appropriate limit for determining sobriety varies depending on local regulations.
- Avoid cross-contamination of urine samples, by using a new specimen collection container for each urine sample.

STORAGE AND STABILITY

Store as packaged in the sealed pouch either at room temperature or refrigerated (2-27°C, 36-80°F). The test strip is stable through the expiration date printed on the sealed pouch. The test strip must remain in the sealed pouch until use. DO NOT FREEZE. Do not use beyond the expiration date.

SPECIMEN COLLECTION AND PREPARATION

The alcohol contained specimens may be stored in a sealed container at 15-27°C (59-80°F) for up to 4 hours prior to testing. Specimens may be refrigerated and stored at 2-8°C (36-46°F). Do not freeze the specimens. Refrigerated specimens should be brought to room temperature before testing.

MATERIALS PROVIDED

- Test strips
- Package insert
- Alcohol Color Chart

MATERIAL REQUIRED BUT NOT PROVIDED

- Timer
- Specimen collection container (for dip tests)

DIRECTIONS FOR USE

1. Bring the pouch to room temperature before opening it. Remove the test strip from the sealed pouch and use it as soon as possible after observing the reaction pad on the test strip. The reaction pad should have a light cream color. Do not use the test strip if the reaction pad has a blue color before the specimen is applied or is otherwise discolored.
2. Saturate the reaction pad with urine from the specimen collection container or by applying the urine directly to the reaction pad. Start the timer immediately after saturating the reaction pad with the specimen.
3. Read results at 2 minutes by visually comparing the color of the reaction pad to the corresponding color blocks printed on the alcohol color chart. DO NOT INTERPRET THE RESULT AFTER 3 MINUTES.

INTERPRETATION OF RESULTS

NEGATIVE: No color change appears on the reaction pad. The color should match the color block on the color chart corresponding to a negative (-) result. This indicates that alcohol has not been detected.

POSITIVE: A color change appears on the reaction pad. The color on the reaction pad varying from a light blue to a dark blue, falling on or between the corresponding color blocks on the color chart. This indicates that alcohol has been detected.

INVALID: The outer edges of the reaction pad produce a slight color but the majority of the reaction pad remains colorless. Repeat the test with a new test strip, ensuring complete saturation of the reaction pad with the specimen. If the problem persists, do not continue the test and contact your local distributor.

QUALITY CONTROL

The Urine Alcohol Test Strip may be qualitatively verified by using a test solution prepared by adding 5 drops of 80 proof distilled spirits to 30 mL of water. This solution should produce a color change on the reaction pad corresponding to 0.02% or greater. The color reaction with alcohol in human urine is somewhat slower and less intense than with alcohol in an aqueous solution. Do not perform the control test with undiluted alcohol, as pure alcohol solutions will not produce a positive result.

LIMITATIONS

1. The Urine Alcohol Test Strip provides only a preliminary result for detection alcohol concentration in human urine. A secondary analytical method must be used to obtain a confirmed result. Gas Chromatography/ Mass Spectrometry (GC/MS) is the preferred confirmatory method.
2. Interpretation of visual results is dependent on several

factors: the variability of color perception, the presence or absence of inhibitory factors, and the lighting conditions when the strip is read. Caution should be taken when interpreting test results due to the subjective nature of the test.
3. The Urine Alcohol Test Strip should not be used to determine the presence of alcohol in beverages, in undiluted alcohol, or in other liquid solutions.
4. Alcohol concentration in human body slowly increases after the alcohol ingestion. Generally, the maximum alcohol concentration in human urine, appears in the range from 30 minutes to 60 minutes after the last alcohol ingestion. After the maximum appearance, the alcohol concentration in the human body reduces. How long the alcohol concentration takes to reduce to zero depends on how much alcohol has been ingested.
5. The Urine Alcohol Test Strip is highly sensitive to the presence of alcohol. Alcohol vapors in the air are sometimes detected by the test strip. Alcohol vapors are present in many institutions and homes. Alcohol is a component in many household products such as disinfectant, deodorizers, perfumes, and glass cleaners. If the presence of alcohol vapors is suspected, the test should be performed in an area known to be free of vapors.
6. Ingestion or general use of over-the-counter medications and products containing alcohol such as cold medicines, breath sprays and mouthwashes can produce positive results. Wait at least 20 minutes after ingesting any such products before using the test strip.

ASSAY SPECIFICITY

The Urine Alcohol Test Strip will react with methyl, ethyl and allyl alcohols. The following substances may interfere with the Urine Alcohol Test Strip. These substances do not normally appear in sufficient quantity in human urine to interfere the test:

Peroxidases	Mercaptans	L-dopa
Strong oxidizers	Tosylates	L-methyldopa
Ascorbic acid	Oxalic acid	Methampyrone
Tannic acid	Uric acid	
Pyrogallol	Bilirubin	

BIBLIOGRAPHY OF SUGGESTED READING

1. Gilman, A. G. and Goodman, L. S., The Pharmacological Basis of Therapeutics, eds. MacMillan Publishing, New York, NY, 1980.
2. Baselt, R. C., Disposition of Toxic Drugs and Chemicals in Man, Biomedical Publications, Davis, CA, 1982.
3. Urine testing for Drugs of Abuse. National Institute on Drug Abuse (NIDA), Research Monograph 73, 1986.
4. Tietz NW. Textbook of Clinical Chemistry. W.B. Saunders Company. 1986; 1735.
5. Hawks RL, CN Chiang. Urine Testing for Drugs of Abuse. National Institute for Drug Abuse (NIDA), Research Monograph 73, 1986.
6. Fed. Register, Department of Health and Human Services, Mandatory Guidelines for Federal Workplace Drug Testing Programs, 53, 69, 11970-11979, 1988.
7. Mikkelsen, S.L. et.al., Clin.Chem. 1988; 34: 648
8. Liu, Ray H. and Goldberger, Bruce A., Handbook of Workplace Drug Testing, AACC Press (1995).
9. Volpicellim, Joseph R., M.D., Ph.D.: Alcohol Dependence: Diagnosis, Clinical Aspects and Biopsychosocial Causes, Substance Abuse Library, University of Pennsylvania, 1997.
10. Hardman J, Limbird LE (Eds). Goodman & Gilman's The Pharmacological Basis of Therapeutics, 10th Ed., McGraw-Hill Publishing. 2001, 1010.

GLOSSARY OF SYMBOLS

CE	European Conformity		Manufacturer
	Consult instructions for use		
REF	Catalog number	EC REP	Authorized representative in European Community

	Use by YYYY-MM		Temperature limitation
	Do not reuse	Σ	Contains sufficient <n>tests
LOT	Batch code	IVD	In vitro diagnostic medical device

Express Diagnostics Int'l, Inc.
1550 Industrial Drive
Blue Earth, MN 56013

EC REP

CEPartner4U
Esdoornlaan 13
3951 DB Maarn
The Netherlands

DC120-FUO English
July 2016

Effective Date: 2016-04-25 DN: 1155942304

One Step Multi-Drug Screen Test Card with the Integrated *i*Cup® / *i*Cup®[A.D.]

Instruction Sheet for testing of any combination of the following drugs:
AMP/BAR/BUP/BZO/COC/THC/MTD/mAMP/
MDMA/MOP/OPI/OXY/PCP/PPX/TCA

Available with Specimen Validity Tests (S.V.T.) for
Oxidants/PCC, Specific Gravity, pH, Nitrite, Glutaraldehyde and Creatinine

A rapid, one step screening test for the simultaneous, qualitative detection of multiple drugs and drug metabolites in human urine.

For healthcare professionals including professionals at point of care sites.

Immunoassay for in vitro diagnostic use only.

INTENDED USE

The **One Step Multi-Drug Screen Test Card with the Integrated *i*Cup®/*i*Cup®[A.D.]** is a lateral flow chromatographic immunoassay for the qualitative detection of multiple drugs and drug metabolites in urine at the following cut-off concentrations:

Test	Calibrator	Cut-off
Amphetamine (AMP 1,000)	d-Amphetamine	1,000 ng/mL
Amphetamine (AMP 300)	d-Amphetamine	300 ng/mL
Barbiturates (BAR)	Secobarbital	300 ng/mL
Benzodiazepines (BZO)	Oxazepam	300 ng/mL
Buprenorphine (BUP)	Buprenorphine	10 ng/mL
Cocaine (COC 300)	Benzoylecgonine	300 ng/mL
Cocaine (COC 150)	Benzoylecgonine	150 ng/mL
Marijuana (THC)	11-nor-Δ^9-THC-9 COOH	50 ng/mL
Methadone (MTD)	Methadone	300 ng/mL
Methamphetamine (mAMP 1,000)	d-Methamphetamine	1,000 ng/mL
Methamphetamine (mAMP 500)	d-Methamphetamine	500 ng/mL
Methylenedioxymethamphetamine (MDMA)	d,l-Methylenedioxymethamphetamine	500 ng/mL
Opiate (MOP 300)	Morphine	300 ng/mL
Opiate (OPI 2,000)	Morphine	2,000 ng/mL
Oxycodone (OXY)	Oxycodone	100 ng/mL
Phencyclidine (PCP)	Phencyclidine	25 ng/mL
Propoxyphene (PPX)	Propoxyphene	300 ng/mL
Tricyclic Antidepressants (TCA)	Nortriptyline	1,000 ng/mL

Configurations of the One Step Multi-Drug Screen Test Card with the Integrated *i*Cup®/*i*Cup®[A.D.] come with any combination of the above listed drug analytes. This assay provides only a preliminary analytical test result. A more specific alternate chemical method must be used in order to obtain a confirmed analytical result. Gas chromatography/mass spectrometry (GC/MS) is the preferred confirmatory method. Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are indicated.

SUMMARY

The **One Step Multi-Drug Screen Test Card with the Integrated *i*Cup®/*i*Cup®[A.D.]** is a rapid urine screening test that can be performed without the use of an instrument. The test utilizes monoclonal antibodies to selectively detect elevated levels of specific drugs in urine.

AMPHETAMINE (AMP 1,000)

Amphetamine is a Schedule II controlled substance available by prescription (Dexedrine®) and is also available on the illicit market. Amphetamines are a class of potent sympathomimetic agents with therapeutic applications. They are chemically related to the human body's natural catecholamines: epinephrine and norepinephrine. Acute higher doses lead to enhanced stimulation of the central nervous system (CNS) and induce euphoria, alertness, reduced appetite, and a sense of increased energy and power. Cardiovascular responses to amphetamines include increased blood pressure and cardiac arrhythmias. More acute responses produce anxiety, paranoia, hallucinations, and psychotic behavior. The effects of Amphetamines generally last 2-4 hours following use and the drug has a half-life of 4-24 hours in the body. About 30% of amphetamines are excreted in the urine in unchanged form, with the remainder as hydroxylated and deaminated derivatives.
The **One Step Multi-Drug Screen Test Card with the Integrated *i*Cup®/*i*Cup®[A.D.]** yields a positive result when the concentration of amphetamines in urine exceeds 1,000 ng/mL.

AMPHETAMINE (AMP 300)

The **One Step Multi-Drug Screen Test Card with the Integrated *i*Cup®/*i*Cup®[A.D.]** yields a positive result when amphetamines in urine exceed 300 ng/mL. See AMPHETAMINE (AMP 1,000) for the summary.

BARBITURATES (BAR)

Barbiturates are CNS depressants. They are used therapeutically as sedatives, hypnotics, and anticonvulsants. Barbiturates are almost always taken orally as capsules or tablets. The effects resemble those of intoxication with alcohol. Chronic use of barbiturates leads to tolerance and physical dependence. Short-acting barbiturates taken at 400 mg/day for 2-3 months can produce a clinically significant degree of physical dependence. Withdrawal symptoms experienced during periods of drug abstinence can be severe enough to cause death.
Only a small amount (less than 5%) of most barbiturates are excreted unaltered in the urine.
The approximate detection time limits for barbiturates are:

Short acting (e.g. Secobarbital)	100 mg PO (oral)	4.5 days
Long acting (e.g. Phenobarbital)	400 mg PO (oral)	7 days[2]

The **One Step Multi-Drug Screen Test Card with the Integrated *i*Cup®/*i*Cup®[A.D.]** yields a positive result when the concentration of barbiturates in urine exceeds 300 ng/mL. At present, the Substance Abuse and Mental Health Services Administration (SAMHSA) does not have a recommended screening cut-off for Barbiturate positive specimens.

BENZODIAZEPINES (BZO)

Benzodiazepines are medications that are frequently prescribed for the symptomatic treatment of anxiety and sleep disorders. They produce their effects via specific receptors involving a neurochemical called gamma aminobutyric acid (GABA). Because they are safer and more effective, benzodiazepines have replaced barbiturates in the treatment of both anxiety and insomnia. Benzodiazepines are also used as sedatives before some surgical and medical procedures, and for the treatment of seizure disorders and alcohol withdrawal.
Risk of physical dependence increases if benzodiazepines are taken regularly (e.g., daily) for more than a few months, especially at higher than normal doses. Stopping abruptly can bring on such symptoms as trouble sleeping, gastrointestinal upset, feeling unwell, loss of appetite, sweating, trembling, weakness, anxiety and changes in perception.
Only trace amounts (less than 1%) of most benzodiazepines are excreted unaltered in the urine; most of the concentration in urine is conjugated drug. The detection period for benzodiazepines in urine is 3-7 days.
The **One Step Multi-Drug Screen Test Card with the Integrated *i*Cup®/*i*Cup®[A.D.]** yields a positive result when the concentration of benzodiazepines in urine exceeds 300 ng/mL. At present, the Substance Abuse and Mental Health Services Administration (SAMHSA) does not have a recommended screening cut-off for benzodiazepine positive specimens.

BUPRENORPHINE (BUP)

Buprenorphine is a potent analgesic often used in the treatment of opioid addiction. The drug is sold under the trade names Subutex™, Buprenex™, Temgesic™ and Suboxone™, which contain Buprenorphine HCl alone or in combination with Naloxone HCl. Therapeutically, Buprenorphine is used as a substitution treatment for opioid addicts. Substitution treatment is a form of medical care offered to opiate addicts (primarily heroin addicts) based on a similar or identical substance to the drug normally used. In substitution therapy, Buprenorphine is as effective as Methadone but demonstrates a lower level of physical dependence. Concentrations of free Buprenorphine and Norbuprenorphine in urine may be less than 1 ng/ml after therapeutic administration, but can range up to 20 ng/ml in abuse situations.[3] The plasma half life of Buprenorphine is 2-4 hours.[3] While complete elimination of a single dose of the drug can take as long as 6 days, the window of detection for the parent drug in urine is thought to be approximately 3 days.
Substantial abuse of Buprenorphine has also been reported in many countries where various forms of the drug are available. The drug has been diverted from legitimate channels through theft, doctor shopping, and fraudulent prescriptions, and been abused via intravenous, sublingual, intranasal and inhalation routes.
The **One Step Multi-Drug Screen Test Card with the Integrated *i*Cup®/*i*Cup®[A.D.]** yields a positive result when the concentration of Buprenorphine in urine exceeds 10 ng/mL. At present, the Substance Abuse and Mental Health Services Administration (SAMHSA) does not have a recommended screening cut-off for buprenorphine positive specimens.

COCAINE (COC 300)

Cocaine is a potent central nervous system stimulant and a local anesthetic. Initially, it brings about extreme energy and restlessness while gradually resulting in tremors, over-sensitivity and spasms. In large amounts, cocaine causes fever, unresponsiveness, difficulty in breathing and unconsciousness.
Cocaine is often self-administered by nasal inhalation, intravenous injection and free-base smoking. It is excreted in the urine in a short time primarily as benzoylecgonine.[4,5] Benzoylecgonine, a major metabolite of cocaine, has a longer biological half-life (5-8 hours) than cocaine (0.5-1.5 hours), and can generally be detected for 24-48 hours after cocaine exposure.[5]
The **One Step Multi-Drug Screen Test Card with the Integrated *i*Cup®/*i*Cup®[A.D.]** yields a positive result when the concentration of benzoylecgonine in urine exceeds 300 ng/mL.

COCAINE (COC 150)

The **One Step Multi-Drug Screen Test Card with the Integrated *i*Cup®/*i*Cup®[A.D.]** yields a positive result when the concentration of benzoylecgonine in urine exceeds 150 ng/mL. This is the suggested screening cut-off for positive specimens set by the Substance Abuse and Mental Health Services Administration (SAMHSA, USA).[1] See COCAINE (COC 300) for the summary.

MARIJUANA (THC)

THC (Δ^9-tetrahydrocannabinol) is the primary active ingredient in cannabis (marijuana). When smoked or orally administered, THC produces euphoric effects. Users have impaired short-term memory and slowed learning. They may also experience transient episodes of confusion and anxiety. Long-term, relatively heavy use may be associated with behavioral disorders. The peak effect of marijuana administered by smoking occurs in 20-30 minutes and the duration is 90-120 minutes after one cigarette. Elevated levels of urinary metabolites are found within hours of exposure and remain detectable for 3-10 days after smoking. The main metabolite excreted in the urine is 11-nor-Δ^9-tetrahydrocannabinol-9-carboxylic acid (THC-COOH).
The **One Step Multi-Drug Screen Test Card with the Integrated *i*Cup®/*i*Cup®[A.D.]** yields a positive result when the concentration of THC-COOH in urine exceeds 50 ng/mL. This is the suggested screening cut-off for positive specimens set by the Substance Abuse and Mental Health Services Administration (SAMHSA, USA).[1]

METHADONE (MTD)

Methadone is a narcotic analgesic prescribed for the management of moderate to severe pain and for the treatment of opiate dependence (heroin, Vicodin, Percocet, morphine). The pharmacology of oral methadone is very different from IV methadone. Oral methadone is partially stored in the liver for later use. IV methadone acts more like heroin. In most states you must go to a pain clinic or a methadone maintenance clinic to be prescribed methadone.
Methadone is a long acting pain reliever producing effects that last from twelve to forty-eight hours. Ideally, methadone frees the client from the pressures of obtaining illegal heroin, from the dangers of injection, and from the emotional roller coaster that most opiates produce. Methadone, if taken for long periods and at large doses, can lead to a very long withdrawal period. The withdrawals from methadone are more prolonged and troublesome than those provoked by heroin cessation, yet the substitution and phased removal of methadone is an acceptable method of detoxification for patients and therapists.[2]
The **One Step Multi-Drug Screen Test Card with the Integrated *i*Cup®/*i*Cup®[A.D.]** yields a positive result when the concentration of methadone in urine exceeds 300 ng/mL. At present, the Substance Abuse and Mental Health Services Administration (SAMHSA) does not have a recommended screening cut-off for methadone positive specimens.

METHAMPHETAMINE (mAMP 1,000)

Methamphetamine is an addictive stimulant drug that strongly activates certain systems in the brain. Methamphetamine is closely related chemically to amphetamine, but the CNS effects of methamphetamine are greater. Methamphetamine is made in illegal laboratories and has a high potential for abuse and dependence. The drug can be taken orally, injected, or inhaled. Acute higher doses lead to enhanced stimulation of the CNS and induce euphoria, alertness, reduced appetite, and a sense of increased energy and power. Cardiovascular responses to methamphetamine include increased blood pressure and cardiac arrhythmias. More acute responses produce anxiety, paranoia, hallucinations, psychotic behavior, and eventually, depression and exhaustion.
The effects of methamphetamine generally last 2-4 hours and the drug has a half-life of 9-24 hours in the body. Methamphetamine is excreted in the urine as amphetamine and oxidized and deaminated derivatives. However, 10-20% of methamphetamine is excreted unchanged. Thus, the presence of the parent compound in the urine indicates methamphetamine use. Methamphetamine is generally detectable in the urine for 3-5 days, depending on urine pH level.
The **One Step Multi-Drug Screen Test Card with the Integrated *i*Cup®/*i*Cup®[A.D.]** yields a positive result when the concentration of methamphetamine in urine exceeds 1,000 ng/mL. This is the historical screening cut-off for positive specimens set by the Substance Abuse and Mental Health Services Administration (SAMHSA, USA).[1]

METHAMPHETAMINE (mAMP 500)

The **One Step Multi-Drug Screen Test Card with the Integrated *i*Cup®/*i*Cup®[A.D.]** yields a positive result when the concentration of methamphetamine in urine exceeds 500 ng/mL. See METHAMPHETAMINE (mAMP 1,000) for the summary.

METHYLENEDIOXYMETHAMPHETAMINE (MDMA)

Methylenedioxymethamphetamine (ecstasy) is a designer drug first synthesized in 1914 by a German drug company for the treatment of obesity.[6] Those who take the drug frequently report adverse effects, such as increased muscle tension and sweating. MDMA is not clearly a stimulant, although it has, in common with amphetamine drugs, a capacity to increase blood pressure and heart rate. MDMA does produce some perceptual changes in the form of increased sensitivity to light, difficulty in focusing, and blurred vision in some users. Its mechanism of action is thought to be via release of the neurotransmitter serotonin. MDMA may also release dopamine, although the general opinion is that this is a secondary effect of the drug (Nichols and Oberlender, 1990). The most pervasive effect of MDMA, occurring in virtually all people who took a reasonable dose of the drug, was to produce a clenching of the jaws.
The **One Step Multi-Drug Screen Test Card with the Integrated *i*Cup®/*i*Cup®[A.D.]** yields a positive result when the concentration of Methylenedioxymethamphetamine in urine exceeds 500 ng/mL. At present, the Substance Abuse and Mental Health Services Administration (SAMHSA) does not have a recommended screening cut-off for Methylenedioxymethamphetamine positive specimens.

OPIATE (MOP 300)

Opiate refers to any drug that is derived from the opium poppy, including the natural products, morphine and codeine, and the semi-synthetic drugs such as heroin. Opioid is more general, referring to any drug that acts on the opioid receptor.
Opioid analgesics comprise a large group of substances which control pain by depressing the CNS. Large doses of morphine can produce higher tolerance levels, physiological dependency in users, and may lead to substance abuse. Morphine is excreted unmetabolized, and is also the major metabolic product of codeine and heroin. Morphine is detectable in the urine for several days after an opiate dose.[2]
The **One Step Multi-Drug Screen Test Card with the Integrated *i*Cup®/*i*Cup®[A.D.]** yields a positive result when the concentration of morphine in urine exceeds 300 ng/mL.

OPIATE (OPI 2,000)

The **One Step Multi-Drug Screen Test Card with the Integrated *i*Cup®/*i*Cup®[A.D.]** yields a positive result when the concentration of morphine in urine exceeds 2,000 ng/mL. This is the suggested screening cut-off for positive specimens set by the Substance Abuse and Mental Health Services Administration (SAMHSA, USA).[1] See OPIATE (MOP 300) for summary.

OXYCODONE (OXY)

Oxycodone is a semi-synthetic opioid with a structural similarity to codeine. The drug is manufactured by modifying thebaine, an alkaloid found in the opium poppy. Oxycodone, like all opiate agonists, provides pain relief by acting on opioid receptors in the spinal cord, brain, and possibly directly in the affected tissues. Oxycodone is prescribed for the relief of moderate to high pain under the well-known pharmaceutical trade names of OxyContin®, Tylox®, Percodan® and Percocet®. While Tylox, Percodan and Percocet contain only small doses of oxycodone hydrochloride combined with other analgesics such as acetaminophen or aspirin, OxyContin consists solely of oxycodone hydrochloride in a time-release form.
Oxycodone is known to metabolize by demethylation into oxymorphone and noroxycodone. In a 24-hour urine, 33-61% of a single, 5 mg oral dose is excreted with the primary constituents being unchanged drug (13-19%), conjugated drug (7-29%) and conjugated oxymorphone (13-14%).[2] The window of detection for oxycodone in urine is expected to be similar to that of other opioids such as morphine.
The **One Step Multi-Drug Screen Test Card with the Integrated *i*Cup®/*i*Cup®[A.D.]** yields a positive result when the concentration of oxycodone in urine exceeds 100 ng/mL. At present, the Substance Abuse and Mental Health Services Administration (SAMHSA) does not have a recommended screening cut-off for oxycodone positive specimens.

PHENCYCLIDINE (PCP)

Phencyclidine, also known as PCP or Angel Dust, is a hallucinogen that was first marketed as a surgical anesthetic in the 1950's. It was removed from the market because patients receiving it became delirious and experienced hallucinations.
PCP is used in powder, capsule, and tablet form. The powder is either snorted or smoked after mixing it with marijuana or vegetable matter. PCP is most commonly administered by inhalation but can be used intravenously, intra-nasally, and orally. After low doses, the user thinks and acts swiftly and experiences mood swings from euphoria to depression. Self-injurious behavior is one of the devastating effects of PCP.
PCP can be found in urine within 4 to 6 hours after use and will remain in urine for 7 to 14 days, depending on factors such as metabolic rate, user's age, weight, activity, and diet.[7] PCP is excreted in the urine as an unchanged drug (4% to 19%) and conjugated metabolites (25% to 30%).[8]
The **One Step Multi-Drug Screen Test Card with the Integrated *i*Cup®/*i*Cup®[A.D.]** yields a positive result when the concentration of phencyclidine in urine exceeds 25 ng/mL. This is the suggested screening cut-off for positive specimens set by the Substance Abuse and Mental Health Services Administration (SAMHSA, USA).[1]

PROPOXYPHENE (PPX)

Propoxyphene (PPX) is a narcotic analgesic compound bearing structural similarity to methadone. As an analgesic, propoxyphene can be from 50-75% as potent as oral codeine. Darvocet™, one of the most common brand names for the drug, contains 50-100 mg of propoxyphene napsylate and 325-650 mg of acetaminophen. Peak plasma concentrations of propoxyphene are achieved from 1 to 2 hours post dose. In the case of overdose, propoxyphene blood concentrations can reach significantly higher levels.
In humans, propoxyphene is metabolized by N-demethylation to yield norpropoxyphene. Norpropoxyphene has a longer half-life (30 to 36 hours) than parent propoxyphene (6 to 12 hours). The accumulation of norpropoxyphene seen with repeated doses may be largely responsible for resultant toxicity.
The **One Step Multi-Drug Screen Test Card with the Integrated *i*Cup®/*i*Cup®[A.D.]** yields a positive result when the concentration of Propoxyphene or Norpropoxyphene in urine exceeds 300 ng/mL. At present, the Substance Abuse and Mental Health Services Administration (SAMHSA) does not have a recommended screening cut-off for propoxyphene positive specimens.

TRICYCLIC ANTIDEPRESSANTS (TCA)

TCA (Tricyclic Antidepressants) are commonly used for the treatment of depressive disorders. TCA overdoses can result in profound CNS depression, cardiotoxicity and anticholinergic effects. TCA overdose is the most common cause of death from prescription drugs. TCAs are taken orally or sometimes by injection. TCAs are metabolized in the liver. Both TCAs and their metabolites are excreted in urine mostly in the form of metabolites for up to ten days.
The **One Step Multi-Drug Screen Test Card with the Integrated *i*Cup®/*i*Cup®[A.D.]** yields a positive result when the concentration of tricyclic antidepressants in urine exceeds 1,000 ng/mL. At present, the Substance Abuse and Mental Health Services Administration (SAMHSA) does not have a recommended screening cut-off for tricyclic antidepressant positive specimens.

S.V.T. SUMMARY

(Information regarding Specimen Validity Tests does not require FDA review.)
The strip contains chemically treated reagent pads. 3-5 minutes following the activation of the reagent pads by the urine sample, the colors that appear on the pads can be compared with the printed color chart card. The color comparison provides a semi-quantitative screen for any combination of oxidants/pyridinium chlorochromate (PCC), specific gravity, pH, nitrite, glutaraldehyde and creatinine in human urine which can help assess the integrity of the urine sample.

WHAT IS ADULTERATION?

Adulteration is the tampering of a urine specimen with the intention of altering the test results. The use of adulterants can cause false negative results in drug tests by either interfering with the screening test and/or destroying the drugs present in the urine. Dilution may also be employed in an attempt to produce false negative drug test results.
One of the best ways to test for adulteration or dilution is to determine certain urinary characteristics such as pH and specific gravity and to detect the presence of oxidants/PCC, specific gravity, pH, nitrite, glutaraldehyde and creatinine in urine.

- **Oxidants/PCC** (Pyridinium chlorochromate) tests for the presence of oxidizing agents such as bleach and hydrogen peroxide. Pyridinium chlorochromate (sold under the brand name UrineLuck) is a commonly used adulterant.[8] Normal human urine should not contain oxidants or PCC.
- **Specific gravity** tests for sample dilution. The normal range is from 1.003 to 1.030. Values outside this range may be the result of specimen dilution or adulteration.
- **pH** tests for the presence of acidic or alkaline adulterants in urine. Normal pH levels should be in the range of 4.0 to 9.0. Values outside of this range may indicate the sample has been altered.
- **Nitrite** tests for commonly used commercial adulterants such as Klear or Whizzies. They work by oxidizing the major cannabinoid metabolite THC-COOH.[9] Normal urine should contain no trace of nitrite. Preliminary positive results generally indicate the presence of an adulterant.
- **Glutaraldehyde** tests for the presence of an aldehyde. Adulterants such as UrinAid and Clear Choice contain glutaraldehyde which may cause false negative screening results by disrupting the enzyme used in some immunoassay tests.[8] Glutaraldehyde is not normally found in urine; therefore, detection of glutaraldehyde in a urine specimen is generally an indicator of adulteration.
- **Creatinine** is a waste product of creatine; an amino-acid contained in muscle tissue and found in urine.[2] A person may attempt to foil a test by drinking excessive amounts of water or diuretics such as herbal teas to "flush" the system. Creatinine and specific gravity are two ways to check for dilution and flushing, which are the most common mechanisms used in an attempt to circumvent drug testing. Low creatinine and specific gravity levels may indicate dilute urine. The absence of creatinine (< 5 mg/dl) is indicative of a specimen not consistent with human urine.

PRINCIPLE

The **One Step Multi-Drug Screen Test Card with the Integrated *i*Cup®/*i*Cup®[A.D.]** is an immunoassay based on the principle of competitive binding. Drugs which may be present in the urine specimen compete against their respective drug conjugate for binding sites on their specific antibody.
During testing, a urine specimen migrates upward by capillary action. A drug, if present in the urine specimen below its cut-off concentration, will not saturate the binding sites of its specific antibody. The antibody will then react with the drug-protein conjugate and a visible colored line will show up in the test region of the specific drug strip. The presence of drug above the cut-off concentration will saturate all the binding sites of the antibody. Therefore, the colored line will not form in the test region.
A drug-positive urine specimen will not generate a colored line in the specific test region of the strip because of drug competition, while a drug-negative urine specimen will generate a line in the test region because of the absence of drug competition.
To serve as a procedural control, a colored line will always appear at the control region, indicating that proper volume of specimen has been added and membrane wicking has occurred.

REAGENTS

Each test contains anti-drug mouse monoclonal antibody and corresponding drug-protein conjugates. The control line contains goat anti-rabbit IgG polyclonal antibodies and rabbit IgG.

S.V.T. REAGENTS

Adulteration Pad	Reactive indicator	Buffers and non-reactive ingredients
Oxidants/PCC	0.36%	99.64%
Specific Gravity	0.25%	99.75%
pH	0.06%	99.94%
Nitrite	0.07%	99.93%
Glutaraldehyde	0.02%	99.98%
Creatinine	0.04%	99.96%

PRECAUTIONS

- For healthcare professionals including professionals at point of care sites.
- Immunoassay for *in vitro* diagnostic use only. Do not use after the expiration date.
- The test cup should remain in the sealed pouch until use.
- All specimens should be considered potentially hazardous and handled in the same manner as an infectious agent.
- The used test cup should be discarded according to federal, state and local regulations.

STORAGE AND STABILITY

Store as packaged in the sealed pouch at 2-30°C (36-86°F). The test is stable through the expiration date printed on the sealed pouch. The test devices must remain in the sealed pouch until use. DO NOT FREEZE. Do not use beyond the expiration date.

SPECIMEN COLLECTION AND PREPARATION

Urine Assay

The urine specimen must be collected in a clean and dry container. Urine collected at any time of the day may be used. Urine specimens exhibiting visible precipitates should be centrifuged, filtered, or allowed to settle to obtain a clear specimen for testing.

Specimen Storage

Urine specimens may be stored at 2-8°C for up to 48 hours prior to testing. For prolonged storage, specimens may be frozen and stored below -20°C. Frozen specimens should be thawed and mixed well before testing. When tests include S.V.T., storage of urine specimens should not exceed 2 hours at room temperature or 4 hours refrigerated prior to testing. For best results, test specimens immediately following collection.

MATERIALS

Materials Provided

- Cups with multi-drug panels [Note: A Fahrenheit temperature strip is affixed to aid in the determination of specimen validity. Please use this temperature strip in conjunction with your Drug Free Policy (if applicable)].
- Adulteration color chart (if applicable)
- Security seal label
- Package insert
- Procedure card

Materials Required But Not Provided

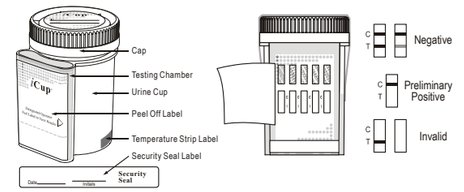
- A timer or any kind of a timing device such as a wrist watch is required to run this test.
- External controls

DIRECTIONS FOR USE

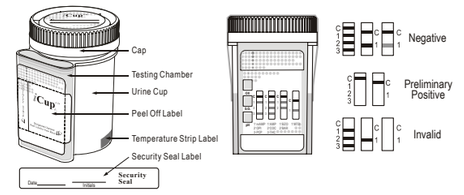
Allow the test cup, urine specimen, and/or controls to equilibrate to room temperature (15-30°C) prior to testing.

1. Bring the pouch to room temperature before opening it. Remove the cup from the sealed pouch and use it as soon as possible.
2. Donor provides specimen.
3. Technician replaces and secures cap while the cup is on a flat surface.
4. Donor dates and initials the security seal and attaches the security seal over the cup cap.
5. Technician peels off label to reveal adulteration strip(s), if applicable.
6. Technician peels off the label on the multi-drug test card to view results.
7. The adulteration strip(s), if applicable, should be read between 3-5 minutes. Compare the colors on the adulteration strip to the color chart. If the results indicate adulteration, do not read the drug test results.
8. If results do not indicate adulteration, read the drug test result at 5 minutes. The drug test results remain stable for up to sixty minutes. See the illustration below. For detailed operation instructions, please refer to the Procedure Card and Color Chart.
9. If preliminary positive results are observed, please send the cup to the laboratory for confirmation.

Cup without SVT



Cup with SVT



INTERPRETATION OF RESULTS

NEGATIVE:* A colored line appears in the Control region (C) and a colored line appears in the Test region (Drug/T) next to a specific drug tested. This negative result means that the drug concentrations in the urine sample are below the designated cut-off levels for a particular drug tested.
***NOTE:** The shade of the colored line(s) in the Test region may vary. The result should be considered negative whenever there is even a faint colored line.
POSITIVE: A colored line appears in the Control region (C) and NO line appears in the Test region (Drug/T) next to the name of a specific drug tested. The positive result means that the drug concentration in the urine sample is greater than the designated cut-off for a specific drug.
INVALID: No line appears in the Control region (C). Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Read the directions again and repeat the test with a new test cup. If the result is still invalid, contact your manufacturer.

SVT/ADULTERANT INTERPRETATION

(Please refer to the color chart)
Semi-quantitative results are obtained by visually comparing the reacted color blocks on the adulteration strips to the printed color blocks on the color chart. No instrumentation is required.

QUALITY CONTROL

A procedural control is included in the test. A line appearing in the Control region (C) is considered an internal procedural control. It confirms sufficient specimen volume, adequate membrane wicking and correct procedural technique.
Control standards are not supplied with this kit. However, it is recommended that positive and negative controls be tested as good laboratory practice to confirm the test procedure and to verify proper test performance.

LIMITATIONS

1. The **One Step Multi-Drug Screen Test Card with the Integrated *i*Cup®/*i*Cup®[A.D.]** provides only a qualitative, preliminary analytical result. A secondary analytical method must be used to obtain a confirmed result. Gas chromatography/mass spectrometry (GC/MS) is the preferred confirmatory method.[1,4,3]
2. There is a possibility that technical or procedural errors, as well as interfering substances in the urine specimen may cause erroneous results.
3. Adulterants, such as bleach and/or alum, in urine specimens may produce erroneous results regardless of the analytical method used. If adulteration is suspected, the test should be repeated with another urine specimen.
4. A positive result does not indicate level or intoxication, administration route or concentration in urine.
5. A negative result may not necessarily indicate drug-free urine. Negative results can be obtained when drug is present but below the cut-off level of the test.
6. This test does not distinguish between drugs of abuse and certain medications.
7. A positive test result may be obtained from certain foods or food supplements.

S.V.T. ADULTERATION LIMITATIONS

1. The adulteration tests, included with this product, are meant to aid in the determination of abnormal specimens. While comprehensive, these tests are not meant to be an all-inclusive representation of possible adulterants.
2. Oxidants/PCC: Normal human urine should not contain oxidants or PCC. The presence of high levels of antioxidants in the specimen, such as ascorbic acid, may result in false negative results for the oxidants/PCC pad.
3. Specific Gravity: Elevated levels of protein in urine may cause abnormally high specific gravity values.
4. Nitrite: Nitrite is not a normal component of human urine. However, nitrite found in urine may indicate urinary tract infections or bacterial infections. Nitrite levels of > 20 mg/dL may produce false preliminary positive glutaraldehyde results.
5. Glutaraldehyde: Is not normally found in urine. However certain metabolic abnormalities such as ketoacidosis (fasting, uncontrolled diabetes or high-protein diets) may interfere with the test results.
6. Creatinine: Normal creatinine levels are between 20 and 350 mg/dL. Under rare conditions, certain kidney diseases may show dilute urine.

PERFORMANCE CHARACTERISTICS

Accuracy

A side-by-side comparison was conducted using the **One Step Multi-Drug Screen Test Card with the Integrated *i*Cup®/*i*Cup®[A.D.]** and commercially available drug rapid tests. Testing was performed on approximately 300 specimens per drug type previously collected from subjects present for drug screen testing. Presumptive positive results were confirmed by GC/MS. The following compounds were quantified by GC/MS and contributed to the total amount of drugs found in presumptive positive urine samples tested.

Test	Compounds Contributing to GC/MS Totals
AMP	Amphetamine
BAR	Secobarbital, Butalbital, Phenobarbital, Pentobarbital
BUP	Buprenorphine
BZO	Oxazepam, Nordiazepam, α-Hydroxyalprazolam, Desalkylflurazepam
COC	Benzoylecgonine
THC	11-nor-Δ^9-tetrahydrocannabinol-9-carboxylic acid
MTD	Methadone
mAMP	Methamphetamine
MDMA	d,l-Methylenedioxymethamphetamine
OPI	Morphine, Codeine
OXY	Oxycodone
PCP	Phencyclidine
PPX	Propoxyphene
TCA	Nortriptyline

The following results are tabulated from these clinical studies:

% Agreement with Commercial Kit

Method			Predicate Test Results		% Agreement with Predicate Test
			Positive	Negative	
One Step Multi-Drug Screen Test Card with the Integrated *i*Cup®/*i*Cup®[A.D.]	AMP 1,000	Positive	129	0	>99%
		Negative	0	172	>99%
	AMP 300	Positive	127	0	>99%
		Negative	0	173	>99%
	BAR	Positive	126	1	>99%
		Negative	0	165	99%
	BUP	Positive	*	*	*
		Negative	*	*	*
	BZO	Positive	131	0	>99%
		Negative	1	162	>99%
	COC 300	Positive	112	1	>99%
		Negative	0	186	99%
	COC 150	Positive	141	0	>99%
		Negative	0	159	>99%
	mAMP 1,000	Positive	121	0	99%
		Negative	1	174	>99%
	mAMP 500	Positive	108	39**	>99%
		Negative	0	153	80%
	MDMA	Positive	86	0	>95%
		Negative	4	152	>99%
	MOP	Positive	125	0	95%
		Negative	7	150	>99%
	MTD	Positive	120	0	87%
		Negative	18	168	>99%
	OPI	Positive	131	0	98%
		Negative	2	164	>99%
	OXY	Positive	135	1	96%
		Negative	5	159	99%
	PCP	Positive	71	0	99%
		Negative	1	160	>99%
	PPX	Positive	157	0	>99%
		Negative	0	157	>99%
	TCA	Positive	45	0	92%
		Negative	4	177	>99%
	THC	Positive	124	1	>99%
		Negative	0	175	99%

* Commercial kit unavailable for BUP
** 32 specimens showed >500 ng/mL concentration by GC/MS

Method		GC/MS					
One Step Multi-Drug Screen Test Card with the Integrated *i*Cup®/*i*Cup®[A.D.]		Neg.	Neg. (< –25% cutoff)	Near cutoff neg. (-25% cutoff to cutoff)	Near cutoff pos. (cutoff to +25% cutoff)	Pos. (> +25% cutoff)	% agreement with GC/MS
AMP 1,000	Positive	0	1	8	18	114	97%
	Negative	149	1	5	4	0	95%
BAR	Positive	0	0	4	5	117	92%
	Negative	150	1	5	1	9	98%
BUP	Positive	0	0	0	5	50	98%
	Negative*	150	15	5	1	0	>99%
BZO	Positive	0	7	1	5	26	97%
	Negative	149	7	1	3	1	95%
COC 300	Positive	0	2	15	16	103	98%
	Negative	150	5	7	1	1	90%
THC	Positive	0	6	3	12	104	95%
	Negative	150	13	6	2	4	95%
MTD	Positive	0	0	10	10	112	99%
	Negative	150	17	0	0	1	94%
mAMP 1,000	Positive	0	0	10	9	126	99%
	Negative	150	0	4	1	0	94%
MDMA	Positive	0	0	3	6	82	>99%
	Negative	147	0	2	0	0	98%
MOP	Positive	0	2	7	10	131	>99%
	Negative	150	0	0	0	0	94%
OPI	Positive	0	0	16	18	116	>99%
	Negative	150	0	0	0	0	90%
PCP	Positive	0	0	6	10	40	>99%
	Negative	150	6	0	0	0	96%
*TCA	Positive	0	12	8	15	20	>99%
	Negative	150	17	0	0	0	89%

* When compared with HP/LC at a cut-off of 1,000ng/ml, the following results were tabulated:

Method		GC/MS				
One Step Multi-Drug Screen Test Card with the Integrated *i*Cup®/*i*Cup®[A.D.]		Neg.	Neg. (< –25% cutoff)	Near cutoff neg. (-25% cutoff to cutoff)	Near cutoff pos. (cutoff to +25% cutoff)	Pos. (> +25% cutoff)	% agreement with GC/MS
*BUP	Positive	0	0	0	5	50	98%
	Negative	150	15	5	1	0	>99%
PPX	Positive	0	0	2	7	158	94%
	Negative	152	5	18	10	0	99%
AMP 300	Positive	0	1	1	2	123	99%
	Negative	150	18	5	0	0	99%
OXY	Positive	0	0	1	2	133	98%
	Negative	147	6	8	0	3	99%

* Negative samples were confirmed negative using LC/MS by pooling these samples into groups of 15.

Method		GC/MS				
One Step Multi-Drug Screen Test Card with the Integrated *i*Cup®/*i*Cup®[A.D.]		Neg.	Near cutoff neg. (-25% cutoff to cutoff)	Near cutoff pos. (cutoff to +25% cutoff)	Pos. (> +25% cutoff)	% agreement with GC/MS
COC 150	Positive	0	0	10	131	>99%
	Negative	150	7	0	2	98%

Method		GC/MS		
One Step Multi-Drug Screen Test Card with the Integrated *i*Cup®/*i*Cup®[A.D.]		Neg.	Pos.	% agreement with GC/MS
mAMP 500	Positive	7	140	>99%
	Negative	153	0	96%

Forty (40) clinical samples for each drug were run using each of the **One Step Multi-Drug Screen Test Card with the Integrated *i*Cup®/*i*Cup®[A.D.]** by an untrained operator at a professional point of care site. Based on GC/MS data, the operator obtained statistically similar positive agreement, negative agreement and overall agreement rates as trained laboratory personnel.

Precision

A study was conducted at three physician offices for Amphetamine (1,000 ng/mL), Cocaine (300 ng/mL), Marijuana, Methamphetamine (1,000 ng/mL), Opiate and Phencyclidine by untrained operators using three different lots of product to demonstrate the within run, between run and between operator precision. An identical panel of coded specimens, containing drugs at the concentration of ± 50% and ± 25% cut-off level, was labeled as a blind and tested at each site. The results are given below:

Drug Conc.	n per site	Site A		Site B		Site C	
		-	+	-	+	-	+
Negative	90	90	0	90	0	90	0
-50% Cut-off	90	90	0	88	2	89	1
-25% Cut-off	90	80	10	70	20	70	20
+25% Cut-off	90	34	56	13	77	12	78
+50% Cut-off	90	5	85	5	85	3	87

A study was conducted at three physician offices for Barbiturates, Benzodiazepines, Methadone, Methylenedioxymethamphetamine, Morphine, and Tricyclic Antidepressants by untrained operators using three different lots of product to demonstrate the within run, between run and between operator precision. An identical panel of coded specimens, containing drugs at the concentration of ± 50% and ± 25% cut-off level, was labeled as a blind and tested at each site. The results are given below:

Drug Conc.	n per site	Site A		Site B		Site C	
		-	+	-	+	-	+
Negative	90	90	0	90	0	90	0
-50% Cut-off	90	83	7	87	3	90	0
-25% Cut-off	90	67	23	75	15	80	10
+25% Cut-off	90	28	62	30	60	22	68
+50% Cut-off	90	1	89	0	90	2	88

A study was conducted at three physician offices by untrained operators using three different lots of product to demonstrate the within run, between run and between operator precision. An identical panel of coded specimens, containing drugs at concentrations of ± 50% and ± 25% cut-off level, was labeled, blinded and tested at each site. The results are given below:

AMPHETAMINE (AMP 300)

Amphetamine conc. (ng/mL)	n per site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	15	15	0	15	0	15	0
150	15	15	0	15	0	15	0
225	15	9	6	14	1	11	4
375	15	1	14	3	12	0	15
450	15	0	15	0	15	0	15

BUPRENORPHINE (BUP)

Buprenorphine conc. (ng/mL)	n per site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	15	15	0	15	0	15	0
5	15	15	0	15	0	15	0
7.5	15	8	7	10	5	9	6
12.5	15	0	15	1	14	0	15
15	15	0	15	0	15	0	15

COCAINE (COC 150)

Benzoylecgonine conc. (ng/mL)	n per site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	15	15	0	15	0	15	0
75	15	15	0	14	1	15	0
112	15	13	2	7	8	15	0
187	15	0	15	0	15	1	14
225	15	0	15	0	15	0	15

METHAMPHETAMINE (mAMP 500)

Methamphetamine conc. (ng/mL)	n per site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	15	15	0	15	0	15	0
250	15	15	0	15	0	15	0
375	15	15	0	10	5	15	0
625	15	1	14	0	15	2	13
750	15	0	15	0	15	0	15

OXYCODONE (OXY)

Oxycodone conc. (ng/mL)	n per site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	15	15	0	15	0	15	0
50	15	15	0	15	0	15	0
75	15	14	1	13	2	11	4
125	15	1	14	0	15	0	15
150	15	0	15	0	15	0	15

PROPOXYPHENE (PPX)

Propoxyphene conc. (ng/mL)	n per site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	15	15	0	15	0	15	0
150	15	15	0	15	0	14	1
225	15	10	5	8	7	7	8
375	15	0	15	0	15	1	14
450	15	0	15	0	15	0	15

Analytical Sensitivity

A drug-free urine pool was spiked with drugs at the listed concentrations. The results are summarized below.

Drug concentration Cut-off Range	n	AMP 1,000		AMP 300		BAR		BZO	
		-	+	-	+	-	+	-	+
0% Cut-off	30	30	0	30	0	30	0	30	0
-50% Cut-off	30	30	0	30	0	30	0	30	0
-25% Cut-off	30	24	6	27	3	25	5	25	5
Cut-off	30	17	13	13	17	13	17	14	16
+25% Cut-off	30	5	25	4	26	7	23	10	20
+50% Cut-off	30	0	30	0	30	0	30	0	30

Drug Concentration Cut-off Range	n	COC 300		COC 150		THC		MTD	
		-	+	-	+	-	+	-	+
0% Cut-off	30	30	0	30	0	30	0	30	0
-50% Cut-off	30	30	0	30	0	30	0	30	0
-25% Cut-off	30	25	5	24	6	27	3	20	10
Cut-off	30	19	11	14	16	14	16	19	11
+25% Cut-off	30	3	27	7	23	6	24	7	23
+50% Cut-off	30	0	30	0	30	0	30	0	30

Drug Concentration Cut-off Range	n	mAMP 1,000		mAMP 500		MDMA		MOP	
		-	+	-	+	-	+	-	+
0% Cut-off	30	30	0	30	0	30	0	30	0
-50% Cut-off	30	30	0	30	0	30	0	30	0
-25% Cut-off	30	24	6	23	7	20	10	27	3
Cut-off	30	18	12	13	17	18	12	17	13
+25% Cut-off	30	5	25	8	22	10	20	10	20
+50% Cut-off	30	0	30	0	30	0	30	0	30

Drug Concentration Cut-off Range	n	OPI		OXY		PCP		PPX		TCA	
		-	+	-	+	-	+	-	+	-	+
0% Cut-off	30	30	0	30	0	30	0	30	0	30	0
-50% Cut-off	30	30	0	30	0	30	0	30	0	30	0
-25% Cut-off	30	25	5	30	0	26	4	24	6	25	5
Cut-off	30	17	13	18	12	14	16	17	13	18	12
+25% Cut-off	30	4	26	6	24	6	24	7	23	5	25
+50% Cut-off	30	0	30	0	30	0	30	0	30	0	30

Drug Concentration Cut-off Range	n	BUP	
		-	+
0% Cut-off	90	90	0
-50% Cut-off	90	90	0
-25% Cut-off	90	75	15
Cut-off	90	60	30
+25% Cut-off	90	31	59
+50% Cut-off	90	0	90

Analytical Specificity

The following table lists the concentrations of compounds (ng/mL) that are detected as positive in urine by the **One Step Multi-Drug Screen Test Card with the Integrated *i*Cup®/*i*Cup®[A.D.]** at 5 minutes.

AMPHETAMINE 1,000 (AMP)	
d-Amphetamine	1,000
d,l-Amphetamine	3,000
l-Amphetamine	50,000
3,4-Methylenedioxyamphetamine (MDA)	2,000
Phentermine	3,000
AMPHETAMINE 300 (AMP)	
d-Amphetamine	300
d,l-Amphetamine	390
l-Amphetamine	50,000
3,4-Methylenedioxyamphetamine (MDA)	1,560
β-Phenylethylamine	100,000
Phenylpropanolamine	100,000
Tyramine	100,000
p-Hydroxynorephedrine	100,000
(±)-Phenylpropanolamine	100,000
p-Hydroxyamphetamine	1,560
d,l-Norephedrine	100,000
BARBITURATES (BAR)	
Secobarbital	300
Amobarbital	300
Alphenal	150
Aprobarbital	200
Butabarbital	75
Butalbital	2,500
Butethal	100
Cyclopentobarbital	600
Pentobarbital	300
Phenobarbital	100
BENZODIAZEPINES (BZO)	
Oxazepam	300
Alprazolam	196
α-Hydroxyalprazolam	1,262
Bromazepam	1,562
Chlordiazepoxide	1,562
Clobazam	98
Clonazepam	781
Clorazepate	195

METHAMPHETAMINE 1,000 (mAMP)	
d-Methamphetamine	1,000
p-Hydroxymethamphetamine	30,000
l-Methamphetamine	8,000
3,4-Methylenedioxymethamphetamine (MDMA)	2,000
Mephentermine	50,000
METHAMPHETAMINE 500 (mAMP)	
d-Methamphetamine	500
d-Amphetamine	50,000
d,l-Amphetamine	75,000
Chloroquine	12,500
3,4-Methylenedioxymethamphetamine (MDMA)	1,000
p-Hydroxymethamphetamine	15,000
Mephentermine	25,000
(1R,2S)-(-)-Ephedrine	50,000
l-Phenylephrine	100,000
β-Phenylethylamine	75,000
METHYLENEDIOXYMETHAMPHETAMINE (MDMA)	
3,4-Methylenedioxymethamphetamine (MDMA)	500
3,4-Methylenedioxyamphetamine (MDA)	3,000
3,4-Methylenedioxyethylamphetamine (MDEA)	300
OPIATE 300 (MOP)	
Morphine	300
Codeine	300
Ethylmorphine	6,250
Hydrocodone	50,000
Hydromorphone	3,125
Levorphanol	1,500
6-Monoacetylmorphine (6-MAM)	400
Morphine 3-β-D-glucuronide	1,000
Norcodeine	6,250
Normorphine	100,000
Oxycodone	30,000
Oxymorphone	100,000
Procaine	15,000
Thebaine	6,250
OPIATE 2,000 (OPI)	
Morphine	2,000

Delorazepam	1,562
Desalkylflurazepam	390
Diazepam	195
Estazolam	2,500
Flunitrazepam	390
(±) Lorazepam	1,562
RS-Lorazepam glucuronide	156
Midazolam	12,500
Nitrazepam	98
Norchlordiazepoxide	195
Nordiazepam	390
Temazepam	98
Triazolam	2,500
BUPRENORPHINE (BUP)	
Buprenorphine	10
Norbuprenorphine	20
Buprenorphine 3-D-glucuronide	15
Norbuprenorphine 3-D-glucuronide	200
COCAINE 300 (COC)	
Benzoylecgonine	300
Cocaine	780
Cocaethylene	12,500
Ecgonine	32,000
COCAINE 150 (COC)	
Benzoylecgonine	150
Cocaine	400
Cocaethylene	6,250
Ecgonine	12,500
Ecgonine methylester	50,000
MARIJUANA (THC)	
11-nor-Δ^9-THC-9 COOH	50
Cannabinol	20,000
11-nor-Δ^8-THC-9 COOH	30
Δ^8–THC	15,000
Δ^9–THC	15,000
METHADONE (MTD)	
Methadone	300
Doxylamine	50,000

Codeine	2,000
Ethylmorphine	5,000
Hydrocodone	12,500
Hydromorphone	5,000
Levorphanol	75,000
6-Monoacetylmorphine (6-MAM)	5,000
Morphine 3-β-D-glucuronide	2,000
Norcodeine	12,500
Normorphine	50,000
Oxycodone	25,000
Oxymorphone	25,000
Procaine	150,000
Thebaine	100,000
OXYCODONE (OXY)	
Oxycodone	100
Naloxone	37,500
Naltrexone	37,500
Levorphanol	50,000
Hydrocodone	6,250
Hydromorphone	50,000
Oxymorphone	200
PHENCYCLIDINE (PCP)	
Phencyclidine	25
4-Hydroxyphencyclidine	12,500
PROPOXYPHENE (PPX)	
d-Propoxyphene	300
d-Norpropoxyphene	300
TRICYCLIC ANTIDEPRESSANTS (TCA)	
Nortriptyline	1,000
Nordoxepin	1,000
Trimipramine	3,000
Amitriptyline	1,500
Promazine	1,500
Desipramine	200
Imipramine	400
Clomipramine	12,500
Doxepin	2,000
Maprotiline	2,000
Promethazine	25,000

Effect of Urinary Specific Gravity

Fifteen (15) urine samples of normal, high, and low specific gravity ranges (1.000-1.037) were spiked with drugs at 50% below and 50% above cut-off levels respectively. The **One Step Multi-Drug Screen Test Card with the Integrated *i*Cup®/*i*Cup®[A.D.]** was tested in duplicate using fifteen drug-free urine and spiked urine samples. The results demonstrate that varying ranges of urinary specific gravity do not affect the test results.

Effect of Urinary pH

The pH of an aliquoted negative urine pool was adjusted to a pH range of 5 to 9 in 1 pH unit increments and spiked with drugs at 50% below and 50% above cut-off levels. The spiked, pH-adjusted urine was tested with the **One Step Multi-Drug Screen Test Card with the Integrated *i*Cup®/*i*Cup®[A.D.]**. The results demonstrate that varying ranges of pH do not interfere with the performance of the test.

Cross-Reactivity

A study was conducted to determine the cross-reactivity of the test with compounds in either drug-free urine or drug positive urine containing, Amphetamine, Barbiturates, Buprenorphine, Benzodiazepines, Cocaine, Marijuana, Methadone, Methamphetamine, Methylenedioxymethamphetamine, Opiate, Oxycodone, Phencyclidine, Propoxyphene or Tricyclic Antidepressants. The following compounds show no cross-reactivity when tested with the **One Step Multi-Drug Screen Test Card with the Integrated *i*Cup®/*i*Cup®[A.D.]** at a concentration of 100 µg/mL.

Non Cross-Reacting Compounds

Acetaminophen
Acetophenetidin
N-Acetylprocainamide
Acetylsalicylic acid
Aminopyrine
Amoxicillin
Ampicillin
l-Ascorbic acid
Apomorphine
Aspartame
Atropine
Benzilic acid
Benzoic acid
Benzphetamine*
Bilirubin
d,l-Brompheniramine
Caffeine
Cannabidol
Chloralhydrate
Chloramphenicol
Chlorothiazide
d,l-Chloropheniramine
Chlorpromazine
Cholesterol
Clonidine
Cortisone
l-Cotinine
Creatinine
Deoxycorticosterone
Dextromethorphan
Diclofenac
Diflunisal
Digoxin
Diphenhydramine
l -Ψ-Ephedrine
β-Estradiol
Estrone-3-sulfate
Ethyl-p-aminobenzoate
l (-)-Epinephrine
Erythromycin
Fenoprofen
Furosemide
Gentisic acid
Hemoglobin
Hydralazine
Hydrochlorothiazide
Hydrocortisone
o-Hydroxyhippuric acid
p-Hydroxytyramine
Ibuprofen
Iproniazid
d,l-Isoproterenol
Isoxsuprine
Ketamine
Ketoprofen
Labetalol
Loperamide
Meperidine
Meprobamate
Methoxyphenamine
Methylphenidate
Nalidixic acid
Naproxen
Niacinamide
Nifedipine
Norethindrone
Noscapine
d,l-Octopamine
Oxalic acid
Oxolinic acid
Oxymetazoline
Papaverine
Penicillin-G
Pentazocine
Perphenazine
Phenelzine
Trans-2-phenylcyclopropylamine
Prednisolone
Prednisone
d,l-Propranolol
d-Pseudoephedrine
Quinacrine
Quinine
Quindine
Rantidine*
Salicylic acid
Serotonin
Sulfamethazine
Sulindac
Tetracycline
Tetrahydrocortisone 3-acetate
Tetrahydrocortisone 3-(β-D-glucuronide)
Tetrahydrozoline
Thiamine
Thioridazine
d,l-Tyrosine
Tolbutamide
Triamterene
Trifluoperazine
Trimethoprim
Tryptamine
d,l-Tryptophan
Uric acid
Verapamil
Zomepirac

*Parent compound only.

BIBLIOGRAPHY

1. Hawks RL, CN Chiang. *Urine Testing for Drugs of Abuse*. National Institute for Drug Abuse (NIDA), Research Monograph 73, 1986.
2. Tietz NW. Textbook of Clinical Chemistry. W.B. Saunders Company. 1986; 1735.
3. Baselt RC. Disposition of Toxic Drugs and Chemicals in Man. 6th Ed. Biomedical Publ., Foster City, CA 2002.
4. Stewart DJ, Inaba T, Lucassen M, Kalow W. *Clin. Pharmacol. Ther.* April 1979; 25 ed: 464, 264-8.
5. Ambre J. *J. Anal. Toxicol.* 1985; 9:241.
6. Winger, Gail, A Handbook of Drug and Alcohol Abuse, Third Edition, Oxford Press, 1992, page 146.
7. FDA Guidance Document: Guidance for Premarket Submission for Kits for Screening Drugs of Abuse to be Used by the Consumer, 1997.
8. Robert DeCresce. *Drug Testing in the workplace*, 1989 page 114.

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Integrated E-Z Split Key® Cup II

Instruction Sheet for testing of any combination of the following drugs:
AMP/BAR/BZO/BUP/COC/THC/MTD/mAMP/MDMA/MOP/OPI/OXY/PCP/PPX/TCA

Available with Specimen Validity Tests (S.V.T.) for Oxidants/PCC, Specific Gravity, pH, Nitrite, Glutaraldehyde and Creatinine.

A rapid, one step screening test for the simultaneous, qualitative detection of multiple drugs and drug metabolites in human urine.

For healthcare professionals including professionals at point of care sites.

Immunoassay for in vitro diagnostic use only.

INTENDED USE

The **Integrated E-Z Split Key® Cup II** is a lateral flow chromatographic immunoassay for the qualitative detection of multiple drugs and drug metabolites in urine at the following cut-off concentrations:

Test	Calibrator	Cut-off
Amphetamine (AMP 1,000)	d-Amphetamine	1,000 ng/mL
Amphetamine (AMP 300)	d-Amphetamine	300 ng/mL
Barbiturates (BAR)	Secobarbital	300 ng/mL
Benzodiazepines (BZO)	Oxazepam	300 ng/mL
Buprenorphine (BUP)	Buprenorphine	10 ng/mL
Cocaine (COC 300)	Benzoylecgonine	300 ng/mL
Cocaine (COC 150)	Benzoylecgonine	150 ng/mL
Marijuana (THC)	11-nor-Δ^9-THC-9 COOH	50 ng/mL
Methadone (MTD)	Methadone	300 ng/mL
Methamphetamine (mAMP 1,000)	d-Methamphetamine	1,000 ng/mL
Methamphetamine (mAMP 500)	d-Methamphetamine	500 ng/mL
Methylenedioxymethamphetamine (MDMA)	d,l-Methylenedioxymethamphetamine	500 ng/mL
Opiate (MOP 300)	Morphine	300 ng/mL
Opiate (OPI 2,000)	Morphine	2,000 ng/mL
Oxycodone (OXY)	Oxycodone	100 ng/mL
Phencyclidine (PCP)	Phencyclidine	25 ng/mL
Propoxyphene (PPX)	Propoxyphene	300 ng/mL
Tricyclic Antidepressants (TCA)	Nortriptyline	1,000 ng/mL

Configurations of the Integrated E-Z Split Key® Cup II come with any combination of the above listed drug analytes. This assay provides only a preliminary analytical test result. A more specific alternate chemical method must be used in order to obtain a confirmed analytical result. Gas chromatography/mass spectrometry (GC/MS) is the preferred confirmatory method. Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are indicated.

SUMMARY

The **Integrated E-Z Split Key® Cup II** is a rapid urine screening test that can be performed without the use of an instrument. The test utilizes monoclonal antibodies to selectively detect elevated levels of specific drugs in urine.

AMPHETAMINE (AMP 1,000)

Amphetamine is a Schedule II controlled substance available by prescription (Dexedrine®) and is also available on the illicit market. Amphetamines are a class of potent sympathomimetic agents with therapeutic applications. They are chemically related to the human body's natural catecholamines: epinephrine and norepinephrine. Acute higher doses lead to enhanced stimulation of the central nervous system (CNS) and induce euphoria, alertness, reduced appetite, and a sense of increased energy and power. Cardiovascular responses to amphetamines include increased blood pressure and cardiac arrhythmias. More acute responses produce anxiety, paranoia, hallucinations, and psychotic behavior. The effects of Amphetamines generally last 2-4 hours following use and the drug has a half-life of 4-24 hours in the body. About 30% of amphetamines are excreted in the urine in unchanged form, with the remainder as hydroxylated and deaminated derivatives.
The **Integrated E-Z Split Key® Cup II** yields a positive result when the concentration of amphetamines in urine exceeds 1,000 ng/mL. This is the historical screening cut-off for positive specimens set by the Substance Abuse and Mental Health Services Administration (SAMHSA, USA).[1]

AMPHETAMINE (AMP 300)

The **Integrated E-Z Split Key® Cup II** yields a positive result when amphetamines in urine exceed 300 ng/mL. See AMPHETAMINE (AMP 1,000) for the summary.

BARBITURATES (BAR)

Barbiturates are CNS depressants. They are used therapeutically as sedatives, hypnotics, and anticonvulsants. barbiturates are almost always taken orally as capsules or tablets. The effects resemble those of intoxication with alcohol. Chronic use of barbiturates leads to tolerance and physical dependence.
Short-acting barbiturates taken at 400 mg/day for 2-3 months can produce a clinically significant degree of physical dependence. Withdrawal symptoms experienced during periods of drug abstinence can be severe enough to cause death.
Only a small amount (less than 5%) of most barbiturates are excreted unaltered in the urine.
The approximate detection time limits for barbiturates are:

Short acting (e.g. Secobarbital)	100 mg PO (oral)	4.5 days
Long acting (e.g. Phenobarbital)	400 mg PO (oral)	7 days[2]

The **Integrated E-Z Split Key® Cup II** yields a positive result when the concentration of barbiturates in urine exceeds 300 ng/mL. At present, the Substance Abuse and Mental Health Services Administration (SAMHSA) does not have a recommended screening cut-off for Barbiturate positive specimens.

BENZODIAZEPINES (BZO)

Benzodiazepines are medications that are frequently prescribed for the symptomatic treatment of anxiety and sleep disorders. They produce their effects via specific receptors involving a neurochemical called gamma aminobutyric acid (GABA). Because they are safer and more effective, benzodiazepines have replaced barbiturates in the treatment of both anxiety and insomnia. Benzodiazepines are also used as sedatives before some surgical and medical procedures, and for the treatment of seizure disorders and alcohol withdrawal.
Risk of physical dependence increases if benzodiazepines are taken regularly (e.g., daily) for more than a few months, especially at higher than normal doses. Stopping abruptly can bring on such symptoms as trouble sleeping, gastrointestinal upset, feeling unwell, loss of appetite, sweating, trembling, weakness, anxiety and changes in perception.
Only trace amounts (less than 1%) of most benzodiazepines are excreted unaltered in the urine; most of the concentration in urine is conjugated drug. The detection period for benzodiazepines in urine is 3-7 days.
The **Integrated E-Z Split Key® Cup II** yields a positive result when the concentration of benzodiazepines in urine exceeds 300 ng/mL. At present, the Substance Abuse and Mental Health Services Administration (SAMHSA) does not have a recommended screening cut-off for benzodiazepine positive specimens.

BUPRENORPHINE (BUP)

Buprenorphine is a potent analgesic often used in the treatment of opioid addiction. The drug is sold under the trade names Subutex™, Buprenex™, Temgesic™ and Suboxone™, which contain Buprenorphine HCl alone or in combination with Naloxone HCl. Therapeutically, Buprenorphine is used as a substitution treatment for opioid addicts. Substitution treatment is a form of medical care offered to opiate addicts (primarily heroin addicts) based on a similar or identical substance to the drug normally used. In substitution therapy, Buprenorphine is as effective as Methadone but demonstrates a lower level of physical dependence. Concentrations of free Buprenorphine and Norbuprenorphine in urine may be less than 1 ng/ml after therapeutic administration, but can range up to 20 ng/ml in abuse situations.[10] The plasma half life of Buprenorphine is 2-4 hours.[10] While complete elimination of a single dose of the drug can take as long as 6 days, the window of detection for the parent drug in urine is thought to be approximately 3 days.
Substantial abuse of Buprenorphine has also been reported in many countries where various forms of the drug are available. The drug has been diverted from legitimate channels through theft, doctor shopping, and fraudulent prescriptions, and been abused via intravenous, sublingual, intranasal and inhalation routes.
The **Integrated E-Z Split Key® Cup II** yields a positive result when the Buprenorphine in urine exceeds 10 ng/mL.At present, the Substance Abuse and Mental Health Services Administration (SAMHSA) does not have a recommended screening cut-off for Buprenorphine positive specimens.

COCAINE (COC 300)

Cocaine is a potent central nervous system stimulant and a local anesthetic. Initially, it brings about extreme energy and restlessness while gradually resulting in tremors, over-sensitivity and spasms. In large amounts, cocaine causes fever, unresponsiveness, difficulty in breathing and unconsciousness.
Cocaine is often self-administered by nasal inhalation, intravenous injection and free-base smoking. It is excreted in the urine in a short time primarily as benzoylecgonine.[3,4] Benzoylecgonine, a major metabolite of cocaine, has a longer biological half-life (5-8 hours) than cocaine (0.5-1.5 hours), and can generally be detected for 24-48 hours after cocaine exposure.[4]
The **Integrated E-Z Split Key® Cup II** yields a positive result when the concentration of benzoylecgonine in urine exceeds 300 ng/mL. This is the historical screening cut-off for positive specimens set by the Substance Abuse and Mental Health Services Administration (SAMHSA, USA).[1]

COCAINE (COC 150)

The **Integrated E-Z Split Key® Cup II** yields a positive result when the concentration of benzoylecgonine in urine exceeds 150 ng/mL. See COCAINE (COC 300) for the summary.
This is the suggested screening cut-off for positive specimens set by the Substance Abuse and Mental Health Services Administration (SAMHSA, USA).[1]

MARIJUANA (THC)

THC (Δ^9-tetrahydrocannabinol) is the primary active ingredient in cannabis (marijuana). When smoked or orally administered, THC produces euphoric effects. Users have impaired short-term memory and slowed learning. They may also experience transient episodes of confusion and anxiety. Long-term, relatively heavy use may be associated with behavioral disorders. The peak effect of marijuana administered by smoking occurs in 20-30 minutes and the duration is 90-120 minutes after one cigarette. Elevated levels of urinary metabolites are found within hours of exposure and remain detectable for 3-10 days after smoking. The main metabolite excreted in the urine is 11-nor-Δ^9-tetrahydrocannabinol-9-carboxylic acid (THC-COOH).
The **Integrated E-Z Split Key® Cup II** yields a positive result when the concentration of THC-COOH in urine exceeds 50 ng/mL. This is the suggested screening cut-off for positive specimens set by the Substance Abuse and Mental Health Services Administration (SAMHSA, USA).[1]

METHADONE (MTD)

Methadone is a narcotic analgesic prescribed for the management of moderate to severe pain and for the treatment of opiate dependence (heroin, Vicodin, Percocet, morphine). The pharmacology of oral methadone is very different from IV methadone. Oral methadone is partially stored in the liver for later use. IV methadone acts more like heroin. In most states you must go to a pain clinic or a methadone maintenance clinic to be prescribed methadone.
Methadone is a long acting pain reliever producing effects that last from twelve to forty-eight hours. Ideally, methadone frees the client from the pressures of obtaining illegal heroin, from the dangers of injection, and from the emotional roller coaster that most opiates produce. Methadone, if taken for long periods and at large doses, can lead to a very long withdrawal period. The withdrawals from methadone are more prolonged and troublesome than those provoked by heroin cessation, yet the substitution and phased removal of methadone is an acceptable method of detoxification for patients and therapists.[2]
The **Integrated E-Z Split Key® Cup II** yields a positive result when the concentration of methadone in urine exceeds 300 ng/mL. At present, the Substance Abuse and Mental Health Services Administration (SAMHSA) does not have a recommended screening cut-off for methadone positive specimens.

METHAMPHETAMINE (mAMP 1,000)

Methamphetamine is an addictive stimulant drug that strongly activates certain systems in the brain. Methamphetamine is closely related chemically to amphetamine, but the CNS effects of methamphetamine are greater. Methamphetamine is made in illegal laboratories and has a high potential for abuse and dependence. The drug can be taken orally, injected, or inhaled. Acute higher doses lead to enhanced stimulation of the CNS and induce euphoria, alertness, reduced appetite, and a sense of increased energy and power. Cardiovascular responses to methamphetamine include increased blood pressure and cardiac arrhythmias. More acute responses produce anxiety, paranoia, hallucinations, psychotic behavior, and eventually, depression and exhaustion.
The effects of methamphetamine generally last 2-4 hours and the drug has a half-life of 9-24 hours in the body. Methamphetamine is excreted in the urine as amphetamine and oxidized and deaminated derivatives. However, 10-20% of methamphetamine is excreted unchanged. Thus, the presence of the parent compound in the urine indicates methamphetamine use. Methamphetamine is generally detectable in the urine for 3-5 days, depending on urine pH level.
The **Integrated E-Z Split Key® Cup II** yields a positive result when the concentration of methamphetamine in urine exceeds 1,000 ng/mL.

METHAMPHETAMINE (mAMP 500)

The **Integrated E-Z Split Key® Cup II** yields a positive result when the concentration of methamphetamine in urine exceeds 500 ng/mL. See METHAMPHETAMINE (mAMP 1,000) for the summary. This is the suggested screening cut-off for positive specimens set by the Substance Abuse and Mental Health Services Administration (SAMHSA, USA).[1]

METHYLENEDIOXYMETHAMPHETAMINE (MDMA)

Methylenedioxymethamphetamine (ecstasy) is a designer drug first synthesized in 1914 by a German drug company for the treatment of obesity.[5] Those who take the drug frequently report adverse effects, such as increased muscle tension and sweating. MDMA is not clearly a stimulant, although it has, in common with amphetamine drugs, a capacity to increase blood pressure and heart rate. MDMA does produce some perceptual changes in the form of increased sensitivity to light, difficulty in focusing, and blurred vision in some users. Its mechanism of action is thought to be via release of the neurotransmitter serotonin. MDMA may also release dopamine, although the general opinion is that this is a secondary effect of the drug (Nichols and Oberlender, 1990). The most pervasive effect of MDMA, occurring in virtually all people who took a reasonable dose of the drug, was to produce a clenching of the jaws.
The **Integrated E-Z Split Key® Cup II** yields a positive result when the concentration of Methylenedioxymethamphetamine in urine exceeds 500 ng/mL.

OPIATE (MOP 300)

Opiate refers to any drug that is derived from the opium poppy, including the natural products, morphine and codeine, and the semi-synthetic drugs such as heroin. Opioid is more general, referring to any drug that acts on the opioid receptor.
Opioid analgesics comprise a large group of substances which control pain by depressing the CNS. Large doses of morphine can produce higher tolerance levels, physiological dependency in users, and may lead to substance abuse. Morphine is excreted unmetabolized, and is also the major metabolic product of codeine and heroin. Morphine is detectable in the urine for several days after an opiate dose.[2]
The **Integrated E-Z Split Key® Cup II** yields a positive result when the concentration of morphine in urine exceeds 300 ng/mL.

OPIATE (OPI 2,000)

The **Integrated E-Z Split Key® Cup II** yields a positive result when the concentration of morphine in urine exceeds 2,000 ng/mL. This is the suggested screening cut-off for positive specimens set by the Substance Abuse and Mental Health Services Administration (SAMHSA, USA).[1] See OPIATE (MOP 300) for summary.

OXYCODONE (OXY)

Oxycodone is a semi-synthetic opioid with a structural similarity to codeine. The drug is manufactured by modifying thebaine, an alkaloid found in the opium poppy. Oxycodone, like all opiate agonists, provides pain relief by acting on opioid receptors in the spinal cord, brain, and possibly directly in the affected tissues. Oxycodone is prescribed for the relief of moderate to high pain under the well-known pharmaceutical trade names of OxyContin®, Tylox®, Percodan® and Percocet®. While Tylox, Percodan and Percocet contain only small doses of oxycodone hydrochloride combined with other analgesics such as acetaminophen or aspirin, OxyContin consists solely of oxycodone hydrochloride in a time-release form.
Oxycodone is known to metabolize by demethylation into oxymorphone and noroxycodone. In a 24-hour urine, 33-61% of a single, 5mg oral dose is excreted with the primary constituents being unchanged drug (13-19%), conjugated drug (7-29%) and conjugated oxymorphone (13-14%).[2] The window of detection for oxycodone in urine is expected to be similar to that of other opioids such as morphine.
The **Integrated E-Z Split Key® Cup II** yields a positive result when the concentration of oxycodone in urine exceeds 100 ng/mL. At present, the Substance Abuse and Mental Health Services Administration (SAMHSA) does not have a recommended screening cut-off for oxycodone positive specimens.

PHENCYCLIDINE (PCP)

Phencyclidine, also known as PCP or Angel Dust, is a hallucinogen that was first marketed as a surgical anesthetic in the 1950's. It was removed from the market because patients receiving it became delirious and experienced hallucinations.
PCP is used in powder, capsule, and tablet form. The powder is either snorted or smoked after mixing it with marijuana or vegetable matter. PCP is most commonly administered by inhalation but can be used intravenously, intra-nasally, and orally. After low doses, the user thinks and acts swiftly and experiences mood swings from euphoria to depression. Self-injurious behavior is one of the devastating effects of PCP.
PCP can be found in urine within 4 to 6 hours after use and will remain in urine for 7 to 14 days, depending on factors such as metabolic rate, user's age, weight, activity, and diet.[6] PCP is excreted in the urine as an unchanged drug (4% to 19%) and conjugated metabolites (25% to 30%).[7]
The **Integrated E-Z Split Key® Cup II** yields a positive result when the concentration of phencyclidine in urine exceeds 25 ng/mL. This is the suggested screening cut-off for positive specimens set by the Substance Abuse and Mental Health Services Administration (SAMHSA, USA).[1]

PROPOXYPHENE (PPX)

Propoxyphene (PPX) is a narcotic analgesic compound bearing structural similarity to methadone. As an analgesic, propoxyphene can be from 50-75% as potent as oral codeine. Darvocet™, one of the most common brand names for the drug, contains 50-100 mg of propoxyphene napsylate and 325-650 mg of acetaminophen. Peak plasma concentrations of propoxyphene are achieved from 1 to 2 hours post dose. In the case of overdose, propoxyphene blood concentrations can reach significantly higher levels.

In humans, propoxyphene is metabolized by N-demethylation to yield norpropoxyphene. Norpropoxyphene has a longer half-life (30 to 36 hours) than parent propoxyphene (6 to 12 hours). The accumulation of norpropoxyphene seen with repeated doses may be largely responsible for resultant toxicity.

The **Integrated E-Z Split Key® Cup II** yields a positive result when the concentration of Propoxyphene or Norpropoxyphene in urine exceeds 300 ng/mL. At present, the Substance Abuse and Mental Health Services Administration (SAMHSA) does not have a recommended screening cut-off for propoxyphene positive specimens.

TRICYCLIC ANTIDEPRESSANTS (TCA)

TCA (Tricyclic Antidepressants) are commonly used for the treatment of depressive disorders. TCA overdoses can result in profound CNS depression, cardiotoxicity and anticholinergic effects. TCA overdose is the most common cause of death from prescription drugs. TCAs are taken orally or sometimes by injection. TCAs are metabolized in the liver. Both TCAs and their metabolites are excreted in urine mostly in the form of metabolites for up to ten days.

The **Integrated E-Z Split Key® Cup II** yields a positive result when the concentration of tricyclic antidepressants in urine exceeds 1,000 ng/mL. At present, the Substance Abuse and Mental Health Services Administration (SAMHSA) does not have a recommended screening cut-off for tricyclic antidepressant positive specimens.

S.V.T. SUMMARY

(Information regarding Specimen Validity Tests does not require FDA review.)

The strip contains chemically treated reagent pads. 3-5 minutes following the activation of the reagent pads by the urine sample, the colors that appear on the pads can be compared with the printed color chart card. The color comparison provides a semi-quantitative screen for any combination of oxidants/pyridinium chlorochromate (PCC), specific gravity, pH, nitrite, glutaraldehyde and creatinine in human urine which can help assess the integrity of the urine sample.

WHAT IS ADULTERATION?

Adulteration is the tampering of a urine specimen with the intention of altering the test results. The use of adulterants can cause false negative results in drug tests by either interfering with the screening test and/or destroying the drugs present in the urine. Dilution may also be employed in an attempt to produce false negative drug test results.

One of the best ways to test for adulteration or dilution is to determine certain urinary characteristics such as pH and specific gravity and to detect the presence of oxidants/PCC, specific gravity, pH, nitrite, glutaraldehyde and creatinine in urine.

- **Oxidants/PCC** (Pyridinium chlorochromate) tests for the presence of oxidizing agents such as bleach and hydrogen peroxide. Pyridinium chlorochromate (sold under the brand name UrineLuck) is a commonly used adulterant.[9] Normal human urine should not contain oxidants or PCC.
- **Specific gravity** tests for sample dilution. The normal range is from 1.003 to 1.030. Values outside this range may be the result of specimen dilution or adulteration.
- **pH** tests for the presence of acidic or alkaline adulterants in urine. Normal pH levels should be in the range of 4.0 to 9.0. Values outside of this range may indicate the sample has been altered.
- **Nitrite** tests for commonly used commercial adulterants such as Klear or Whizzies. They work by oxidizing the major cannabinoid metabolite THC-COOH.[9] Normal urine should contain no trace of nitrite. Positive results generally indicate the presence of an adulterant.
- **Glutaraldehyde** tests for the presence of an aldehyde. Adulterants such as UrinAid and Clear Choice contain glutaraldehyde which may cause false negative screening results by disrupting the enzyme used in some immunoassay tests.[8] Glutaraldehyde is not normally found in urine; therefore, detection of glutaraldehyde in a urine specimen is generally an indicator of adulteration.
- **Creatinine** is a waste product of creatine; an amino-acid contained in muscle tissue and found in urine.[2] A person may attempt to foil a test by drinking excessive amounts of water or diuretics such as herbal teas to "flush" the system. Creatinine and specific gravity are two ways to check for dilution and flushing, which are the most common mechanisms used in an attempt to circumvent drug testing. Low creatinine and specific gravity levels may indicate dilute urine. The absence of creatinine (< 5 mg/dl) is indicative of a specimen not consistent with human urine.

PRINCIPLE

The **Integrated E-Z Split Key® Cup II** is an immunoassay based on the principle of competitive binding. Drugs which may be present in the urine specimen compete against their respective drug conjugate for binding sites on their specific antibody.

During testing, a urine specimen migrates upward by capillary action. A drug, if present in the urine specimen below its cut-off concentration, will not saturate the binding sites of its specific antibody. The antibody will then react with the drug-protein conjugate and a visible colored line will show up in the test region of the specific drug strip. The presence of drug above the cut-off concentration will saturate all the binding sites of the antibody. Therefore, the colored line will not form in the test region.

A drug-positive urine specimen will not generate a colored line in the specific test region of the strip because of drug competition, while a drug-negative urine specimen will generate a line in the test region because of the absence of drug competition.

To serve as a procedural control, a colored line will always appear at the control region, indicating that proper volume of specimen has been added and membrane wicking has occurred.

REAGENTS

Each test line contains anti-drug mouse monoclonal antibody and corresponding drug-protein conjugates. The control line contains goat anti-rabbit IgG polyclonal antibodies and rabbit IgG.

S.V.T. REAGENTS

Adulteration Pad	Reactive indicator	Buffers and non-reactive ingredients
Oxidants/PCC	0.36%	99.64%
Specific Gravity	0.25%	99.75%
pH	0.06%	99.94%
Nitrite	0.07%	99.93%
Glutaraldehyde	0.02%	99.98%
Creatinine	0.04%	99.96%

PRECAUTIONS

- For healthcare professionals including professionals at point of care sites.
- Immunoassay for *in vitro* diagnostic use only. Do not use after the expiration date.
- The test cup should remain in the sealed pouch until use.
- All specimens should be considered potentially hazardous and handled in the same manner as an infectious agent.
- The used test cup should be discarded according to federal, state and local regulations.

STORAGE AND STABILITY

Store as packaged in the sealed pouch at 2°-30°C (36°-86°F). The test is stable through the expiration date printed on the sealed pouch. The test devices must remain in the sealed pouch until use. DO NOT FREEZE. Do not use beyond the expiration date.

SPECIMEN COLLECTION AND PREPARATION

Urine Assay

The urine specimen must be collected in a clean and dry container. Urine collected at any time of the day may be used. Urine specimens exhibiting visible precipitates should be centrifuged, filtered, or allowed to settle to obtain a clear specimen for testing.

Specimen Storage

Urine specimens may be stored at 2-8°C for up to 48 hours prior to testing. For prolonged storage, specimens may be frozen and stored below -20°C. Frozen specimens should be thawed and mixed well before testing. When testing cards with S.V.T. storage of urine specimens should not exceed 2 hours at room temperature or 4 hours refrigerated prior to testing. For best results, rest specimens immediately following collection.

MATERIALS

Materials Provided

- **Integrated E-Z Split Key® Cup II** [Note: A Fahrenheit temperature strip is affixed to aid in the determination of specimen validity. Please use this temperature strip in conjunction with your Drug Free Policy (if applicable)].
- Keys
- Security seals
- Package insert
- Procedure cards
- SVT/Adulterant color charts (Optional)

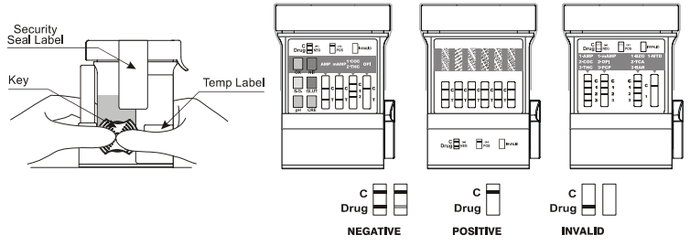
Materials Required But Not Provided

- Timer
- External controls

DIRECTIONS FOR USE

Allow the test cup, urine specimen, and/or controls to equilibrate to room temperature (15-30°C) prior to testing.

1. Bring the pouch to room temperature before opening it. Remove the cup from the sealed pouch and use it as soon as possible.
2. Remove the key by twisting it from the center of the cup cap.
3. **Collect specimen in the cup** and secure cap tightly by pressing down on the pull tab until an audible click is heard.
4. Technician dates and initials the security seal and attaches the security seal over the cup cap.
5. Place the cup on a flat surface and **push the key to a fully closed position** to initiate the test. Start the timer.
6. Remove the peel off label covering the test results.
7. If adulteration is included on the test cup, read the adulteration strip(s) between 3 and 5 minutes. Compare the colors on the adulteration strip to the enclosed color chart. If the specimen indicates adulteration, refer to your Drug Free Policy for guidelines on adulterated specimens. We recommend not to interpret the drug test results and either retest the urine or collect another specimen.
8. **Read the drug strip results at 5 minutes**. The drug test results remain stable for up to sixty minutes.



INTERPRETATION OF RESULTS

NEGATIVE:* A colored line appears in the Control region (C) and a colored line appears in the Test region (Drug/T) next to a specific drug tested. This negative result means that the drug concentrations in the urine sample are below the designated cut-off levels for a particular drug tested.

***NOTE:** The shade of the colored line(s) in the Test region may vary. The result should be considered negative whenever there is even a faint colored line.

POSITIVE: A colored line appears in the Control region (C) and NO line appears in the Test region (Drug/T) next to the name of a specific drug tested. The positive result means that the drug concentration in the urine sample is greater than the designated cut-off for a specific drug.

INVALID: No line appears in the Control region (C). Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Read the directions again and repeat the test with a new test cup. If the result is still invalid, contact your manufacturer.

SVT/ADULTERANT INTERPRETATION

(Please refer to the color chart, if applicable)

Semi-quantitative results are obtained by visually comparing the reacted color blocks on the strip to the printed color blocks on the color chart. No instrumentation is required.

QUALITY CONTROL

A procedural control is included in the test. A line appearing in the Control region (C) is considered an internal procedural control. It confirms sufficient specimen volume, adequate membrane wicking and correct procedural technique.

Control standards are not supplied with this kit. However, it is recommended that positive and negative controls be tested as good laboratory practice to confirm the test procedure and to verify proper test performance.

LIMITATIONS

1. The **Integrated E-Z Split Key® Cup II** provides only a qualitative, preliminary analytical result. A secondary analytical method must be used to obtain a confirmed result. Gas chromatography/mass spectrometry (GC/MS) is the preferred confirmatory method.[1,4,10]
2. There is a possibility that technical or procedural errors, as well as interfering substances in the urine specimen may cause erroneous results.
3. Adulterants, such as bleach and/or alum, in urine specimens may produce erroneous results regardless of the analytical method used. If adulteration is suspected, the test should be repeated with another urine specimen.
4. A positive result does not indicate level or intoxication, administration route or concentration in urine.
5. A negative result may not necessarily indicate drug-free urine. Negative results can be obtained when drug is present but below the cut-off level of the test.
6. This test does not distinguish between drugs of abuse and certain medications.
7. A positive test result may be obtained from certain foods or food supplements.

S.V.T. ADULTERATION LIMITATIONS

1. The adulteration tests, if included with this product, are meant to aid in the determination of abnormal specimens. While comprehensive, these tests are not meant to be an all-inclusive representation of possible adulterants.
2. Oxidants/PCC: Normal human urine should not contain oxidants or PCC. The presence of high levels of antioxidants in the specimen, such as ascorbic acid, may result in false negative results for the oxidants/PCC pad.
3. Specific Gravity: Elevated levels of protein in urine may cause abnormally high specific gravity values.
4. Nitrite: Nitrite is not a normal component of human urine. However, nitrite found in urine may indicate urinary tract infections or bacterial infections. Nitrite levels of > 20 mg/dL may produce false positive glutaraldehyde results.
5. Glutaraldehyde: Is not normally found in urine. However certain metabolic abnormalities such as ketoacidosis (fasting, uncontrolled diabetes or high-protein diets) may interfere with the test results.
6. Creatinine: Normal creatinine levels are between 20 and 350 mg/dL. Under rare conditions, certain kidney diseases may show dilute urine.

PERFORMANCE CHARACTERISTICS

Accuracy

A side-by-side comparison was conducted using the **Integrated E-Z Split Key® Cup II** and commercially available drug rapid tests. Testing was performed on approximately 300 specimens per drug type previously collected from subjects present for drug screen testing. Presumptive positive results were confirmed by GC/MS. The following compounds were quantified by GC/MS and contributed to the total amount of drugs found in presumptive positive urine samples tested.

Test	Compounds Contributing to GC/MS Totals
AMP	Amphetamine
BAR	Secobarbital, Butalbital, Phenobarbital, Pentobarbital
BZO	Oxazepam, Nordiazepam, α-Hydroxyalprazolam, Desalkylflurazepam
BUP	Buprenorphine
COC	Benzoylecgonine
THC	11-nor-Δ^9-tetrahydrocannabinol-9-carboxylic acid
MTD	Methadone
mAMP	Methamphetamine
MDMA	d,l-Methylenedioxymethamphetamine
OPI	Morphine, Codeine
OXY	Oxycodone
PCP	Phencyclidine
PPX	Propoxyphene
TCA	Nortriptyline

The following results are tabulated from these clinical studies:

% Agreement with Commercial Kit

	AMP	AMP 300	BAR	BZO	BUP*	COC 300	COC 150	THC	MTD	mAMP 1,000
Positive Agreement	97%	>99%	>99%	90%	*	95%	>99%	98%	>99%	98%
Negative	>99%	>99%	99%	97%	*	>99%	>99%	>99%	>99%	>99%
Total Results	98%	>99%	99%	94%	*	98%	>99%	99%	>99%	99%

	mAMP 500	MDMA	MOP	OPI	OXY	PCP	PPX	TCA
Positive Agreement	>99%	>99%	>99%	>99%	96%	98%	>99%	95%
Negative Agreement	80%	99%	>99%	>99%	99%	>99%	>99%	>99%
Total Results	87%	99%	>99%	>99%	98%	99%	>99%	99%

* Commercial kit unavailable for BUP

% Agreement with GC/MS

	AMP 1,000	AMP 300	BAR	BZO	BUP*	COC 300	COC 150	THC	MTD
Positive Agreement	97%	>99%	92%	97%	98%	96%	99%	97%	99%
Negative Agreement	95%	99%	98%	95%	>99%	90%	>99%	88%	94%
Total Results	96%	99%	95%	96%	99%	93%	99%	91%	96%

	mAMP 1,000	mAMP 500	MDMA	MOP	OPI	OXY	PCP	PPX	TCA**
Positive Agreement	99%	>99%	>99%	>99%	>99%	98%	>99%	94%	>99%
Negative Agreement	94%	96%	98%	94%	90%	99%	96%	99%	89%
Total Results	96%	98%	99%	97%	95%	99%	97%	96%	91%

Forty (40) clinical samples for each drug were run using each of the **Integrated E-Z Split Key® Cup II** by an untrained operator at a professional point of care site. Based on GC/MS data, the operator obtained statistically similar positive agreement, negative agreement and overall agreement rates as trained laboratory personnel.*Note: BUP was based on LC/MS data. **Note: TCA was based on HPLC data.

Precision

A study was conducted at three physician offices by untrained operators using three different lots of product to demonstrate the within run, between run and between operator precision. An identical panel of coded specimens, containing drugs at concentrations of ± 50% and ± 25% cut-off level, was labeled, blinded and tested at each site. The results are given below:

AMPHETAMINE (AMP 1,000)

Amphetamine conc. (ng/mL)	n per site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	15	15	0	15	0	15	0
500	15	15	0	15	0	14	1
750	15	13	2	11	4	11	4
1,250	15	6	9	4	11	4	11
1,500	15	2	13	1	14	1	14

AMPHETAMINE (AMP 300)

Amphetamine conc. (ng/mL)	n per site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	15	15	0	15	0	15	0
150	15	15	0	15	0	15	0
225	15	9	6	14	1	11	4
375	15	1	14	3	12	0	15
450	15	0	15	0	15	0	15

BARBITURATES (BAR)

Secobarbital conc. (ng/mL)	n per site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	15	15	0	15	0	15	0
150	15	13	2	15	0	15	0
225	15	5	10	7	8	10	5
375	15	2	13	5	10	5	10
450	15	0	15	1	14	1	14

BENZODIAZEPINES (BZO)

Oxazepam conc. (ng/mL)	n per site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	15	15	0	15	0	15	0
150	15	15	0	13	2	13	2
225	15	6	9	7	8	13	2
375	15	0	15	1	14	3	12
450	15	0	15	0	15	0	15

BUPRENORPHINE (BUP)

Buprenorphine conc. (ng/mL)	n per site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	15	15	0	15	0	15	0
5	15	15	0	15	0	15	0
7.5	15	8	7	10	5	9	6
12.5	15	0	15	1	14	0	15
15	15	0	15	0	15	0	15

COCAINE (COC 300)

Benzoylecgonine conc. (ng/mL)	n per site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	15	14*	0	15	0	15	0
150	15	14	1	15	0	14	1
225	15	4	11	5	10	8	7
375	15	0	15	0	15	0	15
450	15	0	15	0	15	1	14

*Note:One invalid result was obtained.

COCAINE (COC 150)

Benzoylecgonine conc. (ng/mL)	n per site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	15	15	0	15	0	15	0
75	15	15	0	14	1	15	0
112	15	13	2	7	8	15	0
187	15	0	15	0	15	1	14
225	15	0	15	0	15	0	15

MARIJUANA (THC)

11-nor-Δ^9-THC-9-COOH conc. (ng/mL)	n per site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	15	15	0	15	0	15	0
25	15	15	0	15	0	14	1
37.5	15	9	6	14	1	9	6
62.5	15	2	13	0	15	0	15
75	15	0	15	0	15	0	15

METHADONE (MTD)

Methadone conc. (ng/mL)	n per site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	15	15	0	15	0	15	0
150	15	12	3	15	0	15	0
225	15	8	7	14	1	15	0
375	15	0	15	0	15	1	14
450	15	1	14	0	15	0	15

METHAMPHETAMINE (mAMP 1,000)

Methamphetamine conc. (ng/mL)	n per site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	15	15	0	15	0	15	0
500	15	15	0	14	1	13	2
750	15	11	4	10	5	10	5
1,250	15	8	7	4	11	6	9
1,500	15	1	14	1	14	0	15

METHAMPHETAMINE (mAMP 500)

Methamphetamine conc. (ng/mL)	n per site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	15	15	0	15	0	15	0
250	15	15	0	15	0	15	0
375	15	15	0	10	5	15	0
625	15	1	14	0	15	2	13
750	15	0	15	0	15	0	15

METHYLENEDIOXYMETHAMPHETAMINE (MDMA) Ecstasy

Methylenedioxymethamphetamine conc. (ng/mL)	n per site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	15	15	0	15	0	15	0
250	15	15	0	15	0	15	0
375	15	15	0	15	0	15	0
625	15	6	9	4	11	7	8
750	15	0	15	0	15	0	15

OPIATE (MOP 300)

Morphine conc. (ng/mL)	n per site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	15	15	0	15	0	15	0
150	15	13	2	13	2	15	0
225	15	3	12	7	8	10	5
375	15	1	14	0	15	1	14
450	15	0	15	1	14	0	15

OPIATE (OPI 2,000)

Morphine conc. (ng/mL)	n per site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	15	15	0	15	0	15	0
1,000	15	15	0	15	0	14	1
1,500	15	13	2	11	4	7	8
2,500	15	4	11	1	14	2	13
3,000	15	0	15	0	15	2	13

OXYCODONE (OXY)

Oxycodone conc. (ng/mL)	n per site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	15	15	0	15	0	15	0
50	15	15	0	15	0	15	0
75	15	14	1	13	2	11	4
125	15	1	14	0	15	0	15
150	15	0	15	0	15	0	15

PHENCYCLIDINE (PCP)

Phencyclidine conc. (ng/mL)	n per site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	15	15	0	15	0	15	0
12.5	15	15	0	14	1	14	1
18.75	15	11	4	13	2	10	5
31.25	15	8	7	5	10	1	14
37.5	15	4	11	0	15	0	15

PROPOXYPHENE (PPX)

Propoxyphene conc. (ng/mL)	n per site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	15	15	0	15	0	15	0
150	15	15	0	15	0	14	1
225	15	10	5	8	7	7	8
375	15	0	15	0	15	1	14
450	15	0	15	0	15	0	15

TRICYCLIC ANTIDEPRESSANTS (TCA)

Nortriptyline conc. (ng/mL)	n per site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	15	15	0	15	0	15	0
500	15	15	0	14	1	15	0
750	15	14	1	11	4	14	1
1,250	15	8	7	2	13	6	9
1,500	15	1	14	0	15	1	14

Analytical Sensitivity

A drug-free urine pool was spiked with drugs at the listed concentrations. The results are summarized below.

Drug concentration Cut-off Range	n	AMP 1,000		AMP 300		BAR		BZO	
		-	+	-	+	-	+	-	+
0% Cut-off	30	30	0	30	0	30	0	30	0
-50% Cut-off	30	30	0	30	0	30	0	30	0
-25% Cut-off	30	22	8	27	3	27	3	27	3
Cut-off	30	12	18	13	17	22	8	11	19
+25% Cut-off	30	2	28	4	26	7	23	5	25
+50% Cut-off	30	0	30	0	30	2	28	0	30

Drug Concentration Cut-off Range	n	COC 300		COC 150		THC		MTD		mAMP1,000	
		-	+	-	+	-	+	-	+	-	+
0% Cut-off	30	30	0	30	0	30	0	30	0	30	0
-50% Cut-off	30	30	0	30	0	30	0	29	1	30	0
-25% Cut-off	30	30	0	24	6	12	18	24	6	30	0
Cut-off	30	4	26	14	16	1	29	21	9	18	12
+25% Cut-off	30	0	30	7	23	1	29	2	28	1	29
+50% Cut-off	30	0	30	0	30	0	30	0	30	0	30

Drug Concentration Cut-off Range	n	mAMP 500		MDMA		MOP		OPI	
		-	+	-	+	-	+	-	+
0% Cut-off	30	30	0	30	0	30	0	30	0
-50% Cut-off	30	30	0	30	0	30	0	30	0
-25% Cut-off	30	23	7	26	4	25	5	30	0
Cut-off	30	13	17	17	13	17	13	13	17
+25% Cut-off	30	8	22	4	26	1	29	4	26
+50% Cut-off	30	0	30	0	30	0	30	0	30

Drug Concentration Cut-off Range	n	OXY		PCP		PPX		TCA	
		-	+	-	+	-	+	-	+
0% Cut-off	30	30	0	30	0	30	0	30	0
-50% Cut-off	30	30	0	30	0	30	0	30	0
-25% Cut-off	30	30	0	19	11	24	6	22	8
Cut-off	30	18	12	16	14	17	13	12	18
+25% Cut-off	30	6	24	6	24	7	23	7	23
+50% Cut-off	30	0	30	0	30	0	30	0	30

Drug Concentration Cut-off Range	n	BUP	
		-	+
0% Cut-off	90	90	0
-50% Cut-off	90	90	0
-25% Cut-off	90	75	15
Cut-off	90	60	30
+25% Cut-off	90	31	59
+50% Cut-off	90	0	90

Analytical Specificity

The following table lists the concentrations of compounds (ng/mL) that are detected as positive in urine by the **Integrated E-Z Split Key® Cup II** at 5 minutes.

Compound	ng/mL
AMPHETAMINE 1,000 (AMP)	
d-Amphetamine	1,000
d,l-Amphetamine	3,000
l-Amphetamine	50,000
3,4-Methylenedioxyamphetamine (MDA)	2,000
Phentermine	3,000
AMPHETAMINE 300 (AMP)	
d-Amphetamine	300
d,l-Amphetamine	390
l-Amphetamine	50,000
3,4-Methylenedioxyamphetamine (MDA)	1,560
β-Phenylethylamine	100,000
Phenylpropanolamine	100,000
Tyramine	100,000
p-Hydroxynorephedrine	100,000
(±)-Phenylpropanolamine	100,000
p-Hydroxyamphetamine	1,560
d,l-Norephedrine	100,000
BARBITURATES (BAR)	
Secobarbital	300
Amobarbital	300
Alphenal	150
Aprobarbital	200
Butabarbital	75
Butalbital	2,500
Butethal	100
Cyclopentobarbital	600
Pentobarbital	300
Phenobarbital	100
BENZODIAZEPINES (BZO)	
Oxazepam	300
Alprazolam	196
α-Hydroxyalprazolam	1,262
Bromazepam	1,562
Chlordiazepoxide	1,562
Clobazam	98
Clonazepam	781
Clorazepate	195
Delorazepam	1,562
Desalkylflurazepam	390
Diazepam	195
Estazolam	2,500
Flunitrazepam	390
(±) Lorazepam	1,562
RS-Lorazepam glucuronide	156
Midazolam	12,500
Nitrazepam	98
Norchlordiazepoxide	195
Nordiazepam	390
Temazepam	98
Triazolam	2,500
BUPRENORPHINE (BUP)	
Buprenorphine	10
Norbuprenorphine	20
Buprenorphine 3-D-glucuronide	15
Norbuprenorphine 3-D-glucuronide	200
COCAINE 300 (COC)	
Benzoylecgonine	300
Cocaine	780
Cocaethylene	12,500
Ecgonine	32,000
COCAINE 150 (COC)	
Benzoylecgonine	150
Cocaine	400
Cocaethylene	6,250
Ecgonine	12,500
Ecgonine methylester	50,000
MARIJUANA (THC)	
11-nor-Δ^9-THC-9 COOH	50
Cannabinol	20,000
11-nor-Δ^8-THC-9 COOH	30
Δ^8–THC	15,000
Δ^9–THC	15,000
METHADONE (MTD)	
Methadone	300
Doxylamine	50,000
METHAMPHETAMINE 1,000 (mAMP)	
d-Methamphetamine	1,000
p-Hydroxymethamphetamine	30,000
l-Methamphetamine	8,000
3,4-Methylenedioxymethamphetamine (MDMA)	2,000
Mephentermine	50,000
METHAMPHETAMINE 500 (mAMP)	
d-Methamphetamine	500
d-Amphetamine	50,000
d,l-Amphetamine	75,000
Chloroquine	12,500
3,4-Methylenedioxymethamphetamine (MDMA)	1,000
p-Hydroxymethamphetamine	15,000
Mephentermine	25,000
(1R,2S)-(-)-Ephedrine	50,000
l-Phenylephrine	100,000
β-Phenylethylamine	75,000
METHYLENEDIOXYMETHAMPHETAMINE (MDMA)	
3,4-Methylenedioxymethamphetamine (MDMA)	500
3,4-Methylenedioxyamphetamine (MDA)	3,000
3,4-Methylenedioxyethylamphetamine (MDEA)	300
OPIATE 300 (MOP)	
Morphine	300
Codeine	300
Ethylmorphine	6,250
Hydrocodone	50,000
Hydromorphone	3,125
Levorphanol	1,500
6-Monoacetylmorphine (6-MAM)	400
Morphine 3-β-D-glucuronide	1,000
Norcodeine	6,250
Normorphine	100,000
Oxycodone	30,000
Oxymorphone	100,000
Procaine	15,000
Thebaine	6,250
OPIATE 2,000 (OPI)	
Morphine	2,000
Codeine	2,000
Ethylmorphine	5,000
Hydrocodone	12,500
Hydromorphone	5,000
Levorphanol	75,000
6-Monoacetylmorphine (6-MAM)	5,000
Morphine 3-β-D-glucuronide	2,000
Norcodeine	12,500
Normorphine	50,000
Oxycodone	25,000
Oxymorphone	25,000
Procaine	150,000
Thebaine	100,000
OXYCODONE (OXY)	
Oxycodone	100
Naloxone	37,500
Naltrexone	37,500
Levorphanol	50,000
Hydrocodone	6,250
Hydromorphone	50,000
Oxymorphone	200
PHENCYCLIDINE (PCP)	
Phencyclidine	25
4-Hydroxyphencyclidine	12,500
PROPOXYPHENE (PPX)	
d-Propoxyphene	300
d-Norpropoxyphene	300
TRICYCLIC ANTIDEPRESSANTS (TCA)	
Nortriptyline	1,000
Nordoxepin	1,000
Trimipramine	3,000
Amitriptyline	1,500
Promazine	1,500
Desipramine	200
Imipramine	400
Clomipramine	12,500
Doxepin	2,000
Maprotiline	2,000
Promethazine	25,000

Effect of Urinary Specific Gravity

Fifteen (15) urine samples of normal, high, and low specific gravity ranges (1.000-1.037) were spiked with drugs at 50% below and 50% above cut-off levels respectively. The **Integrated E-Z Split Key® Cup II** was tested in duplicate using fifteen drug-free urine and spiked urine samples. The results demonstrate that varying ranges of urinary specific gravity do not affect the test results.

Effect of Urinary pH

The pH of an aliquoted negative urine pool was adjusted to a pH range of 5 to 9 in 1 pH unit increments and spiked with drugs at 50% below and 50% above cut-off levels. The spiked, pH-adjusted urine was tested with the **Integrated E-Z Split Key® Cup II**. The results demonstrate that varying ranges of pH do not interfere with the performance of the test.

Cross-Reactivity

A study was conducted to determine the cross-reactivity of the test with compounds in either drug-free urine or drug positive urine containing, Amphetamine, Barbiturates, Benzodiazepines, Buprenorphine, Cocaine, Marijuana, Methadone, Methamphetamine, Methylenedioxymethamphetamine, Opiate, Oxycodone, Phencyclidine, Propoxyphene or Tricyclic Antidepressants. The following compounds show no cross-reactivity when tested with the **Integrated E-Z Split Key® Cup II** at a concentration of 100 µg/mL.

Non Cross-Reacting Compounds

Acetaminophen	Creatinine	Ketoprofen	d-Pseudoephedrine
Acetophenetidin	Deoxycorticosterone	Labetalol	Quinacrine
N-Acetylprocainamide	Dextromethorphan	Loperamide	Quinine
Acetylsalicylic acid	Diclofenac	Meperidine	Quindine
Aminopyrine	Diflunisal	Meprobamate	Rantidine*
Amoxicillin	Digoxin	Methoxyphenamine	Salicylic acid
Ampicillin	Diphenhydramine	Methylphenidate	Serotonin
l-Ascorbic acid	l -Ψ-Ephedrine	Nalidixic acid	Sulfamethazine
Apomorphine	β-Estradiol	Naproxen	Sulindac
Aspartame	Estrone-3-sulfate	Niacinamide	Tetracycline
Atropine	Ethyl-p-aminobenzoate	Nifedipine	Tetrahydrocortisone
Benzilic acid	l (-)-Epinephrine	Norethindrone	3-acetate
Benzoic acid	Erythromycin	Noscapine	Tetrahydrocortisone
Benzphetamine*	Fenoprofen	d,l-Octopamine	3-β-D-glucuronide
Bilirubin	Furosemide	Oxalic acid	Tetrahydrozoline
d,l-Brompheniramine	Gentisic acid	Oxolinic acid	Thiamine
Caffeine	Hemoglobin	Oxymetazoline	Thioridazine
Cannabidol	Hydralazine	Papaverine	d,l-Tyrosine
Chloral hydrate	Hydrochlorothiazide	Penicillin-G	Tolbutamide
Chloramphenicol	Hydrocortisone	Pentazocine	Triamterene
Chlorothiazide	o-Hydroxyhippuric acid	Perphenazine	Trifluoperazine
d,l-Chloropheniramine	p-Hydroxytyramine	Phenelzine	Trimethoprim
Chlorpromazine	Ibuprofen	Trans-2-phenylcyclo propylamine	Tryptamine
Cholesterol	Iproniazid		d,l-Tryptophan
Clonidine	d,l-Isoproterenol	Prednisolone	Uric acid
Cortisone	Isoxsuprine	Prednisone	Verapamil
l-Cotinine	Ketamine	d,l-Propranolol	Zomepirac
Acetaminophen	Creatinine	Ketoprofen	d-Pseudoephedrine

*Parent compound only.

BIBLIOGRAPHY

1. Hawks RL, CN Chiang. *Urine Testing for Drugs of Abuse*. National Institute for Drug Abuse (NIDA), Research Monograph 73, 1986.
2. Tietz NW. Textbook of Clinical Chemistry. W.B. Saunders Company. 1986; 1735.
3. Stewart DJ, Inaba T, Lucassen M, Kalow W. *Clin. Pharmacol. Ther.* April 1979; 25 ed: 464, 264-8.
4. Ambre J. *J. Anal. Toxicol.* 1985; 9:241.
5. Winger, Gail, A Handbook of Drug and Alcohol Abuse, Third Edition, Oxford Press, 1992, page 146.
6. FDA Guidance Document: Guidance for Premarket Submission for Kits for Screening Drugs of Abuse to be Used by the Consumer, 1997.
7. Robert DeCresce. *Drug Testing in the workplace*, 1989 page 114.
8. B. Cody, J.T., "Specimen Adulteration in drug urinalysis. Forensic Sci. Rev., 1990, 2:63.
9. C. Tsai, S.C. et.al., J. Anal. Toxicol. 1998; 22 (6): 474
10. Baselt RC. Disposition of Toxic Drugs and Chemicals in Man. 6th Ed. Biomedical Publ., Foster City, CA 2002.

GLOSSARY OF SYMBOLS

REF Catalog number

Consult instructions for use

Manufacturer

Temperature limitation

LOT Batch code

Use by

Do not reuse

Do not use if package is damaged

Sufficient for (quantity)

EC REP Authorized representative in the European Community

NOTE: The following instructions pertain only to devices that contain an alcohol test strip.

Saliva Alcohol Test

Intended Use

The Saliva Alcohol Test is a rapid, highly sensitive method to detect the presence of alcohol in saliva and provide an approximation of relative blood alcohol concentration. This test provides a preliminary screen only. A more specific alternate chemical method must be used in order to obtain a confirmed analytical result. Clinical consideration and professional judgment should be applied to any test screen result, particularly when preliminary positive screens are indicated.

Summary

Two-thirds of all adults drink alcohol.' The blood alcohol concentration at which a person becomes impaired is variable dependent upon the individual. Each individual has specific parameters that affect the level of impairment such as size, weight, eating habits and alcohol tolerance. Inappropriate consumption of alcohol can be a contributing factor to many accidents, injuries, and medical conditions.

Principle

It is well established that the concentration of alcohol in saliva is comparable to that of blood.[2,3] The Saliva Alcohol Test consists of a plastic strip with a reaction pad attached at the tip. On contact with solutions of alcohol, the reaction pad will rapidly turn colors depending on the concentration of alcohol present. The pad employs a solid-phase chemistry which uses a highly specific enzyme reaction.

Reagents

- Tetramethylbenzidine
- Alcohol Oxidase (EC 1.1.3.13)
- Peroxidase (EC 1.11.1.7)
- Other additives

Precautions

The Saliva Alcohol Test is a visually interpreted test where color matching is used to provide an approximation of relative blood alcohol concentration. Test materials that have been exposed to saliva should be treated as potentially infectious. Do not use the One Step Saliva Alcohol Test after the expiration date marked on the foil package.

Storage and Stability

The Saliva Alcohol Test is to be stored at 2-27°C (36-80°F) in its sealed foil package. If storage temperatures exceed 27°C, the test performance may degrade. If the product is refrigerated, the Saliva Alcohol Test must be brought to room temperature prior to opening the pouch.

Materials Provided

- 25 Individually foil pouched test devices
- Package insert

Materials Required But Not Provided

- Timer

Directions For Use

Allow the pouched strip to equilibrate to room temperature (15-27°C) prior to testing.

1. Abstain from placing anything in the mouth for fifteen (15) minutes prior to beginning the test. This includes non-alcoholic drinks, tobacco products, coffee, breath mints and food, etc.

2. Open the foil package and remove the device. Observe the reactive pad on the end of the test strip. If the reaction pad has a blue color before applying saliva sample, do not use.

3. For specimen collection, follow Procedure instructions on page 2 of this package insert.

4. Saturate the reactive pad with saliva. (It usually takes 6-8 seconds to be saturated.) Start timer immediately after saliva application. Read result at two (2) minutes. Compare the color of the reaction pad with the color chart provided to determine the relative blood alcohol level.

Interpretation of Results

Positive: The Saliva Alcohol Test will produce a color change in the presence of saliva alcohol. The color will range from light blue color at 0.02% relative blood alcohol concentration to a dark blue color near 0.30% relative blood alcohol concentration. Color pads are provided within this range to allow an approximation of relative blood alcohol concentration. The test may produce colors that appear to be between adjacent color pads.

NOTE: The Saliva Alcohol Test is very sensitive to the presence of alcohol. A blue color that is lighter than the 0.02% color pad should be interpreted as being positive to the presence of alcohol in saliva but less than 0.02% relative blood alcohol.

Negative: When the Saliva Alcohol Test shows no color change this should be interpreted as a negative result indicating that alcohol has not been detected.

Invalid: If the color pad has a blue color before applying saliva sample, do not use the test.

NOTE: A result where the outer edges of the color pad produces a slight color but the majority of the pad remains colorless the test should be repeated to ensure complete saturation of the pad with saliva. The test is not reusable.

Limitations

1. Failure to wait 15 minutes after placing food, drink, or other materials (including smoking) in the mouth before running the test can produce erroneous results due to possible contamination of the saliva by interfering substances.

2. The Saliva Alcohol Test is highly sensitive to the presence of alcohol. Alcohol vapors in the air are sometimes detected by the Saliva Alcohol Test. Alcohol vapors are present in many institutions and homes. Alcohol is a component in many household products such as disinfectant, deodorizers, perfumes, and glass cleaners. If the presence of alcohol vapors is suspected, the test should be performed in an area known to be free of vapors.

3. Ingestion or general use of over-the-counter medications and products containing alcohol can produce positive results.

Performance Characteristics

The detection limit on the Saliva Alcohol Test is from 0.02% to 0.30% for approximate relative blood alcohol level. The cutoff level of the Saliva Alcohol Test can vary based on local regulations and laws. Test results can be compared to reference levels with color chart on the foil package.

Assay Specificity

The Saliva Alcohol Test will react with methyl, ethyl and allyl alcohols.

Interfering Substances

The following substances may interfere with the Saliva Alcohol Test when using samples other than saliva. The named substances do not normally appear in sufficient quantity in saliva to interfere with the test.

A. Agents which enhance color development

- Peroxidases
- Strong oxidizers

B. Agents which inhibit color development

- Reducing agents: Ascorbic acid, Tannic acid, Pyrogallol, Mercaptans and tosylates, Oxalic acid, Uric Acid.
- Bilirubin
- L-dopa
- L-methyldopa
- Methampyrone

Controls

The Saliva Alcohol Test may be qualitatively verified by using a test solution prepared by adding 5 drops of 80 proof distilled spirits to 8 oz. (1 cup) of water. This solution should produce a color reaction on the pad. The color reaction with alcohol in saliva is somewhat slower and less intense than with alcohol in an aqueous solution.

Bibliography

1. Volpicellim, Joseph R., M.D., Ph.D.: Alcohol Dependence: Diagnosis, Clinical Aspects and Biopsychosocial Causes., Substance Abuse Library, University of Pennsylvania, 1997.

2. Jones, A.W.: Inter-and intra individual variations in the saliva/blood alcohol ratio during ethanol metabolism in man., Clin. Chem. 25, 1394-1398, 1979.

3. MaCall, L.E.L., Whiting, B., Moore, M.R. and Goldberg, A.: Correlation of ethanol concentrations in blood and saliva., Clin.Sci., 56, 283-286, 1979.

Manufactured For:

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DC202K-FUO 0916

EC REP

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CE

DRUGCHECK® SalivaScan™

FOR FORENSIC USE

INTENDED USE

The DrugCheck® SalivaScan™ Oral Fluid Drug Test is a rapid visual immunoassay for the qualitative, presumptive detection of drugs of abuse in human oral fluid specimens. The test system consists of one or two membrane strips mounted in a plastic cassette.

This test detects combinations of the following drugs at the concentrations listed below. Specific combinations will vary according to the test in question:

Test	Calibrator	Cut-off (ng/mL)
Amphetamine (AMP)	D-Amphetamine	50
Benzodiazepine (BZO)	Oxazepam	50
Buprenorphine (BUP)	Buprenorphine	5
Cocaine (COC)	Benzoylecgonine	20
Cotinine (COT)	Cotinine	50
EDDP (EDDP)	2-Ethyliden-1,5-Dimethyl-3,3-Diphenylpyrrolidine	20
Ketamine (KET)	Ketamine	50
Marijuana (THC)	11-nor-Δ9-THC-9 COOH	12
Marijuana (THC)	Δ9-THC	50
Methadone (MTD)	Methadone	30
Methamphetamine (MET)	D-Methamphetamine	50
Opiates (OPI)	Opiates	40
Oxycodone (OXY)	Oxycodone	40
Phencyclidine (PCP)	Phencyclidine	10
Propoxyphene (PPX)	Propoxyphene	50
Barbiturate (BAR)	Barbiturate	50

PRINCIPLE

The DrugCheck SalivaScan is an immunoassay based on the principle of competitive binding. Drugs that may be present in the oral fluid specimen compete against their respective drug conjugate for binding sites on their specific antibody.

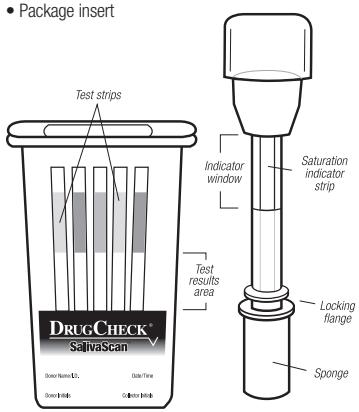
During testing, a portion of the oral fluid specimen migrates upward by capillary action. A drug, if present in the oral fluid specimen below its cut-off concentration, will not saturate the binding sites of its specific antibody. The antibody will then react with the drug-protein conjugate and a visible colored line will show up in the test line region (T) of the specific drug strip. The presence of drug above the cut-off concentration in the oral fluid specimen will saturate all the binding sites of the antibody. Therefore, the colored line will not form in the test line region.

A drug-positive oral fluid specimen will not generate a colored line in the specific test line region of the strip because of drug competition, while a drug-negative oral fluid specimen will generate a line in the test line region because of the absence of drug competition. To serve as a procedural control, a colored line will always appear at the control line region (C), indicating that proper volume of specimen has been added and membrane wicking has occurred.

MATERIALS

Materials Provided

- Individually packed screening devices and oral fluid collection swabs
- Combined Test Procedure/Results Record sheet
- Package insert



Materials Required but Not provided

- Timer
- Positive and negative controls

INTRODUCTION

The DrugCheck SalivaScan for AMP/BAR/BUP/BZO/COC/COT/EDDP/KET/MET/MOR/ MTD/OXY/PCP/PPX/THC parent/THC and metabolites is a rapid,oral fluid screening test that can be performed without the use of an instrument. The test utilizes monoclonal antibodies to selectively detect elevated levels of specific drugs in human oral fluid.

Amphetamine(AMP): Amphetamines (amphetamine, methamphetamine, and the structurally related "designer" drugs, e.g., "Ecstasy") are sympathomimetic amines whose biological effects include potent central nervous system (CNS) stimulation, anorectic, hyperthermic, and cardiovascular properties. They are usually taken orally, intravenously, or by smoking. Amphetamines are readily absorbed from the gastrointestinal tract and are then either deactivated by the liver. Amphetamines increase the heart rate and blood pressure and suppress the appetite. Some studies indicate that heavy abuse may result in permanent damage to certain essential nerve structures in the brain.

Benzodiazepine(BZO): Benzodiazepines are medications that are frequently prescribed for the symptomatic treatment of anxiety and sleep disorders. They produce their effects via specific receptors involving a neurochemical called gamma aminobutyric acid (GABA). Because they are safer and more effective, Benzodiazepines have replaced Barbiturates in the treatment of both anxiety and insomnia. Benzodiazepines are also used as sedatives before some surgical and medical procedures, and for the treatment of seizure disorders and alcohol withdrawal.

Benzoylecgonine/Cocaine(COC): Derived from leaves of the coca plant, cocaine is a potent central nervous system stimulant and a local anesthetic. Among the psychological effects induced by using cocaine are euphoria, confidence and a sense of increased energy, accompanied by increased heart rate, dilation of the pupils, fever, tremors and sweating. Cocaine is excreted in saliva primarily as benzoylecgonine in a short period of time.

Buprenorphine(BUP): Buprenorphine is a potent analgesic often used in the treatment of opioid addiction. The drug is sold under the trade names Subutex™, Buprenex™,Temgesic™ and Suboxone™,which contain Buprenorphine HCl alone or in combination whith Naloxone HCl. Therapeutically, Buprenorphine is used as a substitution treatment for opioid addicts.Substitution treatment is a form of medical care offered to opiate addicts(primarily heroin addicts)based on a similar or identical substance to the drug normally used. In substitution therapy, Buprenorphine is as effective as Methadone but demonstrates a lower level of physical dependence.Concentrations of free Buprenorphine and Norbuprenorphine in saliva may be less than 1 ng/ml after therapeutic administration,but can range up to 20 ng/ml in abuse situations. The plasma half-life of Buprenorphine is 2-4 hours.While complete elimination of a single-dose of the drug can take as long as 6 days, the detection window for the parent drug in urine is thought to be approximately 3 days.

Cotinine(COT): Cotinine is the first-stage metabolite of nicotine, a toxic alkaloid that produces stimulation of the autonomic ganglia and central nervous system when in humans. Nicotine is a drug to which virtually every member of a tobacco-smoking society is exposed whether through direct contact or second-hand inhalation. In addition to tobacco, nicotine is also commercially available as the active ingredient in smoking replacement therapies such as nicotine gum, transdermal patches and nasal sprays.

EDDP(EDDP): Methadone (MTD) is a synthetic analgesic drug that is originally used in the treatment of narcotic addicts. Among the psychological effects induced by using methadone are analgesia,sedation and respiratory depression.Overdose of methadone may cause coma or even death. It is administered orally or intravenously and is metabolized in the liver. The kidneys are a major route of methadone excretion. Methadone has a biological half-life of 16-50 hours. EDDP (2-Ethyliden-1,5-Dimethyl-3,3-Diphenylpyrrolidine) is the most important metabolite of methadone. It is excreted into the bile and urine together with the other metabolite EMDP (2-Ethyl-5-Methyl-3,3-Diphenylpyrrolidine). EDDP is formed by N-demethylation and cyclization of methadone in the liver. The part of the unchanged excreted methadone is variable and depends on the urine's pH value,dose,and the patient's metabolism.Therefore, the detection of the metabolite EDDP instead of methadone itself is useful, because interferences of the patient's metabolism are avoided.

Ketamine (KET): Ketamine is a derivative of phencyclidine. It is used medically as a veterinary and human anaesthetic since 1970. About 90 percent of the ketamine legally sold is intended for veterinary use. It can be injected or snorted, but is sometimes sprinkled on tobacco or marijuana and smoked. Ketamine is frequently used in combination with other drugs, such as ecstasy, heroin or cocaine. Ketamine is also known as "special K" or "vitamin K." Certain doses of Ketamine can cause dream-like states and hallucinations. In high dose, ketamine can cause delirium, amnesia, impaired motor function, high blood pressure, depression, and potentially fatal respiratory problems. Ketamine is metabolized in the liver and excreted through the kidney.

Marijuana(THC): Tetrahydrocannabinol, the active ingredient in the marijuana plant (cannabis sativa), is detectable in saliva shortly after use. The detection of the drug is thought to be primarily due to the direct exposure of the drug to the mouth (oral and smoking administrations) and the subsequent sequestering of the drug in the buccal cavity3. Historical studies have shown a window of detection for THC in saliva of up to 14 hours after drug use3. The Marijuana THC 12 assay yields a positive result when the THC-COOH concentration exceeds 12 ng/mL. The Marijuana THC 50 assay yields a positive result when the Δ9-THC concentration exceeds 50 ng/mL.

Methadone(MTD): Methadone is a synthetic analgesic drug that is originally used in the treatment of narcotic addicts. Among the psychological effects induced by using methadone are analgesia, sedation and respiratory depression. Overdose of methadone may cause coma or even death. It is administered orally or intravenously and is metabolized in the liver. The kidneys are a major route of methadone excretion.

Methamphetamine(MET): Methamphetamine and its metabolites are potent sympathomimetic agents. Acute higher doses lead to enhanced stimulation of the central nervous system and symptoms include euphoria, alertness, and a sense of increased energy and power. More acute responses produce anxiety, paranoia, psychotic behavior, and cardiac dysrhythmias. The pattern of psychosis which may appear at high doses may be indistinguishable from schizophrenia.

Opiates/Morphine(OPI): Opiates such as heroin, morphine, and codeine are derived from the resin of opium poppy. Heroin is quickly metabolized to morphine. Thus, morphine and morphine glucuronide might both be found in the saliva of a person who has taken only heroin. The body also changes codeine to morphine. Thus the presence of morphine (or the metabolite, morphine glucuronide) in the saliva often indicates heroin, morphine and/or codeine use.

Oxycodone(OXY): Oxycodone is a semi-synthetic opioid with a structural similarity to codeine. The drug is manufactured by modifying thebaine, an alkaloid found in the opium poppy. Oxycodone, like all opiate agonists, provides pain relief by acting on opioid receptors in the spinal cord, brain, and possibly directly in the affected tissues. Oxycodone is prescribed for the relief of moderate to high pain under the well-known pharmaceutical trade names of OxyContin®, Tylox®, Percodan® and Percocet®. While Tylox, Percodan and Percocet contain only small doses of oxycodone hydrochloride combined with other analgesics such as acetaminophen or aspirin, OxyContin consists solely of oxycodone hydrochloride in a time-release form. Oxycodone is known to metabolize by demethylation into oxymorphone and noroxycodone.

Phencyclidine (PCP): Phencyclidine is an arylcyclohexylamine that was originally used as an anesthetic agent and a veterinary tranquilizer. Phencyclidine can produce hallucinations, lethargy, disorientation, loss of coordination, trance-like ecstatic states, a sense of euphoria and visual distortions. It has many street names, such as “angel dust” and “crystal cyclone”, etc. Phencyclidine can be administered orally, by nasal ingestion, smoking, or intravenous injection. It is metabolized in the liver and excreted through the kidneys.

Barbiturate(BAR): Barbiturates are central nervous system depressants. They are used therapeutically as sedatives, hypnotics, and anticonvulsants. Barbiturates are almost always taken orally as capsules or tablets. The effects resemble those of intoxication with alcohol. Chronic use of Barbiturates leads to tolerance and physical dependence. Short acting Barbiturates taken at 400 mg/day for 2-3 months produce a clinically significant degree of physical dependence. Withdrawal symptoms experienced during periods of drug abstinence can be severe enough to cause death.

Propoxyphene(PPX): Propoxyphene or Dextropropoxyphene is a narcotic analgesic compound with a structural similarity to methadone. It is prescribed in the United States for the relief of moderate pain. Darvocet™, one of the most common brand names for the drug, contains 50-100 mg of propoxyphene napsylate and 325-650 mg of acetaminophen. Physiological effects of propoxyphene include respiratory depression. Propoxyphene is metabolized in the liver to yield norpropoxyphene. Norpropoxyphene has a longer half-life (30 to 36 hours) than that of propoxyphene (6 to 12 hours). Norpropoxyphene demonstrates substantially less central-nervous system depression than propoxyphene, but shows a greater local anesthetic effect.

PRECAUTIONS

For forensic use only.

• Do not use after the expiration date indicated on the package. Do not use the test if the foil pouch is damaged. Do not reuse tests.

• This kit contains products of animal origin. Certified knowledge of the origin and/or sanitary state of the animals does not completely guarantee the absence of transmissible pathogenic agents. It is therefore, recommended that these products be treated as potentially infectious, and handled by observing usual safety precautions (e.g., do not ingest or inhale).

• Read the entire procedure carefully prior to testing.

• Do not eat, drink or smoke in the area where specimens and kits are handled. Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout the procedure and follow standard procedures for the proper disposal of specimens. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed.

• Humidity and temperature can adversely affect results.

• Used testing materials should be discarded in accordance with local regulations.

STORAGE AND STABILITY

• The kit should be stored at 2-30°C until the expiry date printed on the sealed pouch.

• The test must remain in the sealed pouch until use.

• Do not freeze.

• Kits should be kept out of direct sunlight.

• Care should be taken to protect the components of the kit from contamination. Do not use if there is evidence of microbial contamination or precipitation. Biological contamination of dispensing equipment, containers or reagents can lead to false results.

SPECIMEN COLLECTION AND STORAGE

• This device is intended for use with human oral fluid specimens only.

• Oral fluid specimens must be collected according to the directions in the Procedure section of this package insert.

• Perform testing immediately after specimen collection.

• If specimens are to be shipped, pack them in compliance with all applicable regulations for transportation of etiological agents.

PROCEDURE

Bring tests, specimens, and/or controls to room temperature (15-30°C) before use. Donors should avoid placing anything (including food, drink, gum and tobacco products) in their mouth for at least 10 minutes prior to specimen collection.

1. Using the provided collection swab, have donor sweep inside of mouth (cheek, gums, tongue) several times, then hold swab in mouth until color on the saturation indicator strip appears in the indicator window of collection swab. Donor must leave swab in mouth until instructed to remove it.

NOTE: If at 7 minutes, color on the saturation indicator has not appeared in the indicator window, proceed with the test – #2 below.

2. Remove collection swab from mouth and insert it sponge first into the screening device, pushing until the locking flange locks in place in the bottom of the device.

3. Set device upright on flat surface and keep upright while test is running. Wait for the colored bands to appear in test results area. Negative results can be read as soon as two lines appear on any test strip (often within 2 minutes). Read presumptive positive results at 10 minutes. Do not interpret results after 20 minutes.

NOTE: Once the collection swab locks in place, the device is airtight, tamper evident, and ready to be disposed or sent to lab for confirmation (on presumptive positive result).

INTERPRETATION OF RESULTS

(See previous illustration)

POSITIVE: Only one colored band appears, in the control region (C). No colored band appears in the test region (T) for the drug in question. A positive result indicates that the drug concentration exceeds the detectable level.

NEGATIVE: Two colored bands appear on the membrane. One band appears in the control region (C) and another band appears in the test region (T) for the drug in question. A negative result indicates that the drug concentration is below the detectable level.

INVALID: Control band fails to appear. Results from any test which has not produced a control band at the specified read time must be discarded. Please review the procedure and repeat with a new test. If the problem persists, discontinue using the kit immediately and contact your local distributor.

NOTE: 1. The intensity of color in the test region (T) may vary depending on the concentration of analytes present in the specimen. Therefore, any shade of color in the test region (T) should be considered negative. Please note that this is a qualitative test only, and cannot determine the concentration of analytes in the specimen.

2. Insufficient specimen volume, incorrect operating procedure or expired tests are the most likely reasons for control band failure.

QUALITY CONTROL

• Internal procedural controls are included in the test. A colored band appearing in the control region (C) is considered an internal positive procedural control, confirming sufficient specimen volume and correct procedural technique.

• External controls are not supplied with this kit. It is recommended that positive and negative controls be tested as a good laboratory practice to confirm the test procedure and to verify proper test performance.

LIMITATIONS OF THE TEST

1. This device is for forensic use, and should be only used for the qualitative detection of drugs of abuse in oral fluid.

2. This assay provides a preliminary analytical test result only. A more specific alternative chemical method must be used in order to obtain a confirmed analytical result. Gas chromatography/mass spectrometry (GC/MS) has been established as the preferred confirmatory method by the National Institute on Drug Abuse (NIDA). Clinical consideration and professional judgment should be applied to any test result, particularly when preliminary positive results are indicated.

3. There is a possibility that technical or procedural errors as well as other substances and factors may interfere with the test and cause false results.

4. A positive result indicates the presence of a drug/metabolite only, and does not indicate or measure intoxication.

5. A negative result does not at any time rule out the presence of drugs/metabolites in urine, as they may be present below the minimum detection level of the test.

6. This test does not distinguish between drugs of abuse and certain medications.

PERFORMANCE CHARACTERISTICS

A. Sensitivity

A phosphate-buffered saline (PBS) pool was spiked with drugs to target concentrations of ±50% cut-off and ±25% cut-off and tested with this device. The results are summarized below.

Drug Conc. (Cut-off range)	n	AMP		BUP		BZO		COC	
		-	+	-	+	-	+	-	+
0% Cut-off	30	30	0	30	0	30	0	30	0
-50% Cut-off	30	30	0	30	0	30	0	30	0
-25% Cut-off	30	30	0	28	2	30	0	29	1
Cut-off	30	12	18	13	17	14	16	12	18
+25% Cut-off	30	2	28	4	26	4	26	2	28
+50% Cut-off	30	0	30	0	30	0	30	0	30

Drug Conc. (Cut-off range)	n	COT		EDDP		KET		MET	
		-	+	-	+	-	+	-	+
0% Cut-off	30	30	0	30	0	30	0	30	0
-50% Cut-off	30	30	0	30	0	30	0	30	0
-25% Cut-off	30	30	0	30	0	27	3	30	0
Cut-off	30	11	19	13	17	9	21	13	17
+25% Cut-off	30	1	29	2	28	3	27	3	27
+50% Cut-off	30	0	30	0	30	0	30	0	30

Drug Conc. (Cut-off range)	n	MTD		OPI		OXY		PCP	
		-	+	-	+	-	+	-	+
0% Cut-off	30	30	0	30	0	30	0	30	0
-50% Cut-off	30	30	0	30	0	30	0	30	0
-25% Cut-off	30	30	0	28	2	28	2	28	2
Cut-off	30	10	20	10	20	10	20	11	19
+25% Cut-off	30	2	28	9	21	4	26	5	25
+50% Cut-off	30	0	30	0	30	0	30	0	30

Drug Conc. (Cut-off range)	n	THC		THC parent		BAR		PPX	
		-	+	-	+	-	+	-	+
0% Cut-off	30	30	0	30	0	30	0	30	0
-50% Cut-off	30	30	0	30	0	30	0	30	0
-25% Cut-off	30	30	0	30	0	27	3	30	0
Cut-off	30	10	20	10	20	9	21	10	20
+25% Cut-off	30	5	25	4	26	3	27	4	26
+50% Cut-off	30	0	30	0	30	0	30	0	30

B. Specificity

The following table lists the concentrations of compounds (ng/mL) above which the device identified positive results at 10 minutes.

	Concen. (ng/mL)
Amphetamine-Related Compounds	
D-Amphetamine	50
L-Amphetamine	4,000
(+)-3,4-Methylene-dioxyamphetamine (MDA)	150
Phentermine	40,000
PMA	125
Tyramine	3,000
Benzodiazepine-Related Compounds	
Oxacepam	10
Alprazolam	15
Bromazepam	8
Chlordiazepoxide	10
Clonazepam	40
Clorazepate	20
Clbazam	6
Diazepam	15
Estazolam	10
Desalkyflurazepam	8
Flunitrazepam	10
Flurazepam	10
Lorazepam	20
Medazepam	10
Nitrazepam	10
Nordiazepam	6
Prazepam	20
Temazepam	8
Triazola	15
Buprenorphine -Related Compounds	
Buprenorphine	5
Buprenorphine Glucuronide	10
Buprenorphine–3–b–D–Glucuronide	5
Norbuprenorphine	10
Norbuprenorphine–3–b–D–Glucuronide	200
Cocaine-Related Compounds	
Benzoylecgonine	20
Cocaine	20
Ecgonine	4,000
Ecgonine methyl ester	10,000
Cotinine-Related Compounds	
Cotinine	50
Buprenorphine	>100,000
EDDP -Related Compounds	
EDDP	20
Meperidine	20,000
Methadone	20,000
Norfentanyl	20,000
Phencyclidine	20,000
Promazine	10,000
Promethazine	5,000
Prothipendyl	10,000
Prozine	2,500
Ketamine-Related Compounds	
Ketamine(KET)	50
Norketamine	50
Dextromethorphan	25
Dextrorphan tartrate	25
D-Norpropoxyphene	1560
Meperidine	750
Mephentermine hemisulfate salt	1000
D-Methamphetamine	750
3,4-Methylenedioxy-ethylamphetamine (MDEA)	1500
Nordoxepin hydrochloride	1500
Phencyclidine	250
Promazine	400
Promethazine	1250
Marijuana -Related Compounds	
11-nor-D9 -THC-9 COOH	12
D8-Tetrahydrocannabinol	2,000
D9-Tetrahydrocannabinol	4,000
11-hydroxy-D9 -THC	300
D9-Tetrahydrocannabinol	50
D8-Tetrahydrocannabinol	75
11-nor-D9 -THC-9 COOH	12
11-hydroxy-D9 -THC	300
Cannabinol	2,000
Cannabidiol	>10,000
Methadone -Related Compounds	
Methadone	30
Alpha-Methadol	125
Biperiden	80,000
Doxylamine	12,500
2-Ethylidene-1,5-dimethyl-3,3-diphenylpyrolidine (EDDP)	10,000
Phencyclidine	12,500
Pheniramine	25,000
Methamphetamine-Related Compounds	
D-Methamphetamine	50
Fenfluramine	3,000
L-Methamphetamine	500
L-Phenylephrine	2,500
MDEA	400
3,4-Methylenedioxy-methamphetamine (MDMA)	75
Mephentermine	200
PMMA	50
Procaine	2,500
Opiates -Related Compounds	
Morphine	40
Codeine	10
Diacetylmorphine (Heroin)	50
Ethylmorphine	24
Hydrocodone	50
Hydromorphone	100
6-Monoacetylmorphine (6-MAM)	25
Morphine-3-b-d-glucuronide	50
Nalorphine	10,000
Oxycodone	25,000
Oxymorphone	25,000
Thebaine	5,000
Oxycodone-Related Compounds	
Oxycodone	40
Hydrocodone	1000
Hydromorphone	6250
Naloxone	6250
Oxymorphone	1000
Phencyclidine-Related Compounds	
Phencyclidine (PCP)	10
Hydrocodone	2,000
Hydromorphone	2,000
Morphine-3-b-d-glucuronide	20,000
Nalorphine	10,000
Propoxyphene -Related Compounds	
Propoxyphene (PPX)	50
D-Norpropoxyphene	200
Barbiturate -Related Compounds	
Barbiturate (BAR)	50
Allobarbital	200
Alphenal	100
Amobarbital	100
Aprobarbital	30
Butabarbital	15
Butalbital	400
Butethal	30
Cyclopentobarbital	60
Pentobarbital	150
Phenobarbital	300

A study was conducted to determine the cross-reactivity of the test with compounds spiked into drug-free PBS stock. The following compounds demonstrated no false positive results on the device when tested atconcentrations up to 100 ug/mL.

Aspirin	4-Dimethylaminoantipyrine	Midazolam
Albumine	Diphenhydramine	Mirtazapin
Atropine	Doxepin	Metoclopramide
Alphenal	D-Propoxyphene	N-Methylephedrine
a-hydroxyalprazolam	DL-Tyrosine	Nordoxepinhydrochloride
Alprazolam	Dopamine	(±)-Norketamine
Amantadine	DL-Tryptophan	Nortriptyline
Amikacin	EDDP	Olanzapine
Aminopyrine	Erythromycine	Opipramol
Amitriptyline	Estron 3 sulfate	Oxalic acid
Atenolol	Ethanol	Oxymetazoline
Amoxicilline	Etodolac	Paroxetine
Ampicilline	(+)-Ephedrine	Pemoline
Apomorphine	(-)-Ephedrine	Pennicilline G
Aspartame	(±)-Epinephrine	Perphenazine
Baclofen	Fentanyl	Phenothiazine
Barbital	Flupentixol	(±)-Phenylpropanolamine
Benzocaine	Fluoxetine	b-Phenylethylamine
Bilirubin	Furosemide	Phenytoin
Butethal	Gastrozepin	Prednisolone
Carbamazepine	Gentamicin	Prednisone
Cephalexin	Gentisic acid	Protriptyline
(-)-Cotinine	Guaiacol Glyceryl Ether	Quetiapine
Creatinine	Glucose	Quinidine
Creatine	Haloperidol	Ranitidine
Chloramphenicol	Hemoglobin	Rifampicine
Chloroquine	Hexobarbital	Risperidone
Chlorpheniramine	Hydralazine	Salbutamol
Chlorprothixene	Hydrochlorothiazide	Salicylic acid
Cholesterol	Hydrocortisone	Secobarbital
Chorptothixene	Ibuprofen	Sertraline
Cimetidine	Imipramine	Sodium chloride
Ciprofloxacin	Indomethacin	Spironolactone
Citalopram	Insulin	Sulfamethoxazole
Clindamycin	(-)Isoproterenol	Sulindac
Clobazam	Kanamycin	Theophylline
Clomipramine	Ketamine	Thiamine
Clonidine	Ketoprofen	Thioridazine
Clozapine	L-Thyroxine	Tobramycin
Caffeine	Lincomycin	Triazolam
Cyclobenzaprine	Loperamide	Triamterene
Delorazepam	Lidocaine	Trimethoprim
Desipramine	Lindane	Trimipramine
DL-Propanolol	Lormetazepam	Valproic acid
Digoxin	Metoprolol	Vancomycin
Dihydrocodeine	Methadone	Venlafaxine
(+)-cis-Diltiazem	Maprotiline	Verapamil
Dimenhydrinate	Metronidazole	Zolpidem

LITERATURE REFERENCES

1. Baselt RC. Disposition of Toxic Drugs and Chemicals in Man. 2nd ed. Davis: Biomedical Publications; 1982.

2. Hawks RL, Chiang CN, eds. Urine Testing for Drugs of Abuse. Rockville: Department of Health and Human Services, National Institute on Drug Abuse; 1986.

3. Substance Abuse and Mental Health Services Administration. Mandatory Guidelines for Federal Workplace Drug Testing Programs. 53 Federal Register; 1988.

4. McBay AJ. Drug-analysis technology--pitfalls and problems of drug testing. Clin Chem. 1987 Oct; 33 (11 Suppl): 33B-40B.

5. Gilman AG, Goodman LS, Gilman A, eds. Goodman and Gilman’s The Pharmacological Basis of Therapeutics. 6th ed. New York: Macmillan; 1980.

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*i*Screen® OFD Drug Test Device

Package Insert for the AMP/mAMP/COC/OPI/THC/PCP/OXY Test for Oral Fluids

A rapid, screening test for the simultaneous, qualitative detection of amphetamine, methamphetamine, cocaine, opiates, marijuana, phencyclidine and oxycodone and their metabolites in human oral fluid.

For Forensic Use Only

INTENDED USE

The **Alere *i*Screen® OFD Drug Test Device** for AMP/mAMP/COC/OPI/THC/PCP/OXY is a lateral flow chromatographic immunoassay for the qualitative detection of amphetamine, methamphetamine, cocaine, opiates, marijuana, phencyclidine and oxycodone and their metabolites in oral fluids at the following cut-off concentrations:

Test	Calibrator	Cut-off
Amphetamine (AMP)	d-Amphetamine	50 ng/mL
Methamphetamine (mAMP)	d-Methamphetamine	50 ng/mL
Cocaine (COC)	Benzoylecgonine	20 ng/mL
Opiates (OPI)	Morphine	40 ng/mL
Marijuana (THC)	11-nor-Δ^9-THC-9 COOH	12 ng/mL
Phencyclidine (PCP)	Phencyclidine	10 ng/mL
Oxycodone (OXY)	Oxycodone	20 ng/mL

This assay provides only a preliminary analytical test result. A more specific alternate chemical method must be used in order to obtain a confirmed analytical result. Gas chromatography/mass spectrometry (GC/MS), gas chromatography/tandem mass spectrometry (GC/MS/MS) and liquid chromatography/tandem mass spectrometry (LC/MS/MS) are the preferred confirmatory methods. Professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are indicated.

SUMMARY

The **Alere *i*Screen® OFD Drug Test Device** for AMP/mAMP/COC/OPI/THC/PCP/OXY and their metabolites is a rapid, oral fluid screening test that can be performed without the use of an instrument. The test utilizes antibodies to selectively detect elevated levels of specific drugs in human oral fluid.

Amphetamine (AMP)

Amphetamine is a sympathomimetic amine with therapeutic indications. The drug is often self-administered by nasal inhalation or oral ingestion. Depending on the route of administration, amphetamine can be detected in oral fluid as early as 5-10 minutes and up to 72 hours after use.[1]

The Amphetamine assay contained within the **Alere *i*Screen® OFD Drug Test Device** yields a positive result when the amphetamine concentration in oral fluid exceeds 50 ng/mL.

Methamphetamine (mAMP)

Methamphetamine is a potent stimulant chemically related to amphetamine but with greater central nervous system (CNS) stimulation properties. The drug is often self-administered by nasal inhalation, smoking or oral ingestion. Depending on the route of administration, methamphetamine can be detected in oral fluid as early as 5-10 minutes and up to 72 hours after use.[1]

The Methamphetamine assay contained within the **Alere *i*Screen® OFD Drug Test Device** yields a positive result when the methamphetamine concentration in oral fluid exceeds 50 ng/mL.

Cocaine (COC)

Cocaine is a potent CNS stimulant and a local anesthetic derived from the coca plant (erythroxylum coca). The drug is often self-administered by nasal inhalation, intravenous injection and free-base smoking. Depending on the route of administration, cocaine and its metabolites, benzoylecgonine and ecgonine methylester, can be detected in oral fluid as early as 5-10 minutes and up to 24 hours after use.[1]

The Cocaine assay contained within the ***i*Screen® OFD Drug Test Device** yields a positive result when the cocaine metabolite concentration in oral fluid exceeds 20 ng/mL.

Opiates (OPI)

The drug class opiates refers to any drug that is derived from the opium poppy, including naturally occurring compounds such as morphine and codeine and semi-synthetic drugs such as heroin. Opiates act to control pain by depressing the central nervous system. The drugs demonstrate addictive properties when used for sustained periods of time; symptoms of withdrawal may include sweating, shaking, nausea and irritability. Opiates can be taken orally or by injection routes including intravenous, intramuscular and subcutaneous; illegal users may also take the drug intravenously or by nasal inhalation. Using an immunoassay cutoff level of 40 ng/mL, codeine can be detected in the oral fluid within 1 hour following a single oral dose and can remain detectable for 7-21 hours after the dose.[2] 6-Monoacetylmorphine (6-MAM) is found more prevalently in oral fluid, and is a metabolic product of heroin. Morphine is a major metabolic product of codeine and heroin, and is detectable for 24-48 hours following an opiate dose.

The Opiates assay contained within the **Alere *i*Screen® OFD Drug Test Device** yields a positive result when the morphine concentration in oral fluid exceeds 40 ng/mL.

Marijuana (THC)

Tetrahydrocannabinol (THC), the active ingredient in the marijuana plant (*cannabis sativa*), is detectable in oral fluid shortly after use. The detection of the drug is thought to be primarily due to the direct exposure of the drug to the mouth (oral and smoking administrations) and the subsequent sequestering of the drug in the buccal cavity.[3] Historical studies have shown a window of detection for THC in oral fluid of up to 14 hours after drug use.[3]

The THC assay contained within the **Alere *i*Screen® OFD Drug Test Device** yields a positive result when the 11-nor-Δ^9-THC-9 COOH concentration in oral fluid exceeds 12 ng/mL.

Phencyclidine (PCP)

Phencyclidine (PCP), the hallucinogen commonly referred to as Angel Dust, can be detected in oral fluid as a result of the exchange of the drug between the circulatory system and the oral cavity. In a paired serum and oral fluid sample collection of 100 patients in a hospital emergency department, PCP was detected in the oral fluid of 79 patients at levels as low as 2 ng/mL and as high as 600 ng/mL.[4]

The Phencyclidine assay contained within the **Alere *i*Screen® OFD Drug Test Device** yields a positive result when the PCP concentration in oral fluid exceeds 10 ng/mL.

Oxycodone (OXY)

Oxycodone is a semi-synthetic opioid with a structural similarity to codeine. The drug is manufactured by modifying thebaine, an alkaloid found in the opium poppy. Oxycodone, like all opiate agonists, provides pain relief by acting on opioid receptors in the spinal cord, brain, and possibly directly in the affected tissues. Oxycodone is prescribed for the relief of moderate to high pain under the well-known pharmaceutical trade names of OxyContin®, Tylox®, Percodan® and Percocet®. While Tylox, Percodan and Percocet contain only small doses of oxycodone hydrochloride combined with other analgesics such as acetaminophen or aspirin, OxyContin consists solely of oxycodone hydrochloride in a time-release form. The approximate half- life in serum is averaged about 14 hours.

The Oxycodone assay contained within the **Alere *i*Screen® OFD Drug Test Device** for yields a positive result when the oxycodone concentration in oral fluid exceeds 20 ng/mL.

ASSAY PRINCIPLE

The **Alere *i*Screen® OFD Drug Test Device** for AMP/mAMP/COC/OPI/THC/PCP/OXY is an immunoassay based on the principle of competitive binding. Drugs that may be present in the oral fluid specimen compete against their respective drug conjugates for binding sites on their specific antibody.

During testing, a portion of the oral fluid specimen migrates upward by capillary action. A drug, if present in the oral fluid specimen below its cut-off concentration, will not saturate the binding sites of its specific antibody. The antibody will then react with the drug-protein conjugate and a visible colored line will show up in the test line region of the specific drug strip. The presence of drug above the cut-off concentration in the oral fluid specimen will saturate all the binding sites of the antibody. Therefore, the colored line will not form in the test line region.

A drug-positive oral fluid specimen will not generate a colored line in the specific test line region of the strip because of drug competition, while a drug-negative oral fluid specimen will generate a line in the test line region because of the absence of drug competition.

To serve as a procedural control, a colored line will always appear at the control line region, indicating that proper volume of specimen has been added and membrane wicking has occurred.

REAGENTS

The test contains membrane strips coated with drug-protein conjugates on the test line, polyclonal antibody against gold-protein conjugate at the control line, and a dye pad which contains colloidal gold particles coated with antibody specific to Amphetamine, Methamphetamine, Benzoylecgonine, Morphine, 11-nor-Δ^9-THC-9 COOH, Phencyclidine and Oxycodone.

PRECAUTIONS

- The device is **for forensic use only**.
- Do not use after the expiration date.
- The oral fluid test device should remain in the sealed pouch until use.
- Saliva is not classified as biological hazard unless derived from a dental procedure.
- The used collector and device should be discarded according to federal, state and local regulations.

STORAGE AND STABILITY

Store as packaged in the sealed pouch at 2-30°C. The test is stable through the expiration date printed on the sealed pouch. The test devices must remain in the sealed pouch until use. DO NOT FREEZE. Do not use beyond the expiration date.

SPECIMEN COLLECTION AND PREPARATION

The oral fluid specimen should be collected using the collector provided with the kit, following the detailed instructions under Directions for Use. No other collection devices should be used with this assay. Oral fluid collected at any time of the day may be used.

MATERIALS

Materials Provided

- Test devices
- Caps
- Sponge protectors
- Procedure cards
- Security seals
- Package insert

Materials Required but not Provided

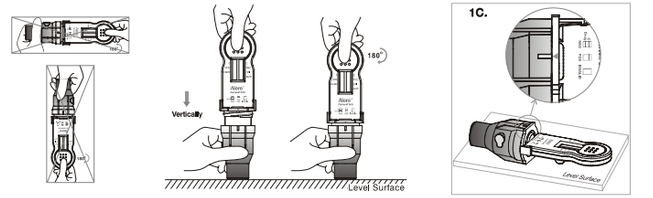
- Timer

DIRECTIONS FOR USE

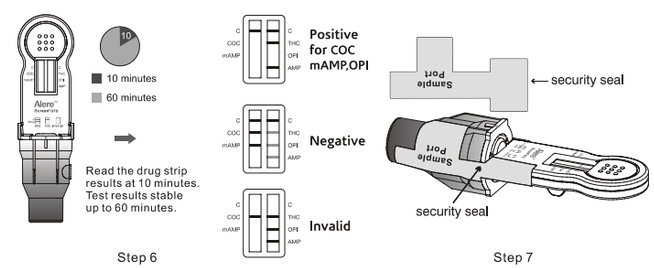
Allow the Alere *i*Screen® OFD Drug Test Device to come to room temperature [15-30°C (59-86°F)] prior to testing. Instruct the donor not to place anything in the mouth including food, drink, gum, or tobacco products for at least 10 minutes prior to collection.

1. Bring the pouch to room temperature before opening it. Remove the test and Cap from the sealed pouch and use the test as soon as possible.
2. Remove the Sample Collector Protector from the collection Sponge. Instruct the donor to insert the Sponge end of the collector into the mouth and actively swab the inside of the mouth and the top of the tongue. As soon as the Sponge softens slightly, the donor should gently press the Sponge between the tongue and teeth to ensure **complete saturation**.
3. The Sponge is saturated when no hard spots can be felt. Collect for a total of at least three (3) minutes before removing the Sponge. Remove the collector from the mouth
4. Align the **Red Arrow** on the device with one of the **White Marks** on the Cap. Insert the collector **vertically** into the Cap and **press down firmly**. Twist the Cap clockwise 180° until the **Red Arrow** lines up with the other **White Mark**.
5. Place the test device horizontally on a clean and level surface with facing up.
6. **Read results at 10 minutes**. Do not read results after 1 hour.
7. If positive results are observed, secure Cap with security seal and send the device to a laboratory for confirmation. The laboratory can access the reservoir through the Sample Port.
8. For detailed operating instructions, please refer to the Procedure Card.

Step 1 Step 2 Step 3



Step 4 Step 5



Step 6 Step 7

INTERPRETATION OF RESULTS

(Please refer to the previous illustration)

NEGATIVE:* All test lines appear. One colored line should be in the control region (C), and other apparent colored line should be adjacent in the test region (Drug/T). This negative result indicates that the drug concentration is below the detectable level or drug free.

***NOTE**: The shade of color in the test region (Drug/T) will vary, but it should be considered negative whenever there is even a faint colored line.

POSITIVE: One colored line appears in the control region (C). Any test line not appears in the test region (Drug/T). This positive result indicates that the drug concentration is above the detectable level.

INVALID: Control line fails to appear. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test using a new test panel. If the problem persists, discontinue using the lot immediately and contact the manufacturer.

QUALITY CONTROL

A procedural control is included in the test. A colored line appearing in the control region (C) is considered an internal procedural control. It confirms sufficient specimen volume, adequate membrane wicking and correct procedural technique.

LIMITATIONS

1. The **Alere *i*Screen® OFD Drug Test Device** provides only a qualitative, preliminary analytical result. A secondary analytical method must be used to obtain a confirmed result. Gas chromatography/mass spectrometry (GC/MS), gas chromatography/tandem mass spectrometry (GC/MS/MS) or liquid chromatography/tandem mass spectrometry (LC/MS/MS) are preferred confirmatory methods.
2. A positive test result does not indicate the concentration of drug in the specimen or the route of administration.
3. A negative result may not necessarily indicate a drug-free specimen. Drug may be present in the specimen below the cutoff level of the assay.

PERFORMANCE CHARACTERISTICS

Analytical Sensitivity

A PBS pool was spiked with drugs to target concentrations of ± 50% cut-off and ± 25% cut-off and tested with the **Alere *i*Screen® OFD Drug Test Device**. The results are summarized below.

Drug Conc. (Cut-off range)	AMP		COC		THC		mAMP		OPI		PCP		OXY	
	-	+	-	+	-	+	-	+	-	+	-	+	-	+
0% Cut-off	30	0	30	0	30	0	30	0	30	0	30	0	90	0
-50% Cut-off	30	0	30	0	30	0	30	0	30	0	30	0	90	0
-25% Cut-off	26	4	30	0	24	6	28	2	26	4	30	0	90	0
Cut-off	19	11	20	10	15	15	23	7	20	10	22	8	53	37
+25% Cut-off	7	23	6	24	11	19	7	23	5	25	8	22	0	90
+50% Cut-off	0	30	0	30	0	30	0	30	0	30	0	30	0	90

Analytical Specificity

The following table lists the concentration of compounds (ng/mL) above which the **Alere *i*Screen® OFD Drug Test Device** for AMP/mAMP/COC/OPI/THC/PCP/OXY identified positive results at a read time of 10 minutes.

COCAINE (COC)	
Benzoylecgonine	20
Cocaine	20
Cocaethylene	25
Ecgonine	1,500
Ecgonine methylester	12,500
AMPHETAMINE (AMP)	
d-Amphetamine	50
d,l-Amphetamine	125
β-Phenylethylamine	4,000
Tryptamine	1,500
p-Hydroxyamphetamine	800
(+) 3,4-Methylenedioxyamphetamine (MDA)	150
l-Amphetamine	4,000
METHAMPHETAMINE (mAMP)	
d-Methamphetamine	50
Fenfluramine	60,000
p-Hydroxymethamphetamine	400
Methoxyphenamine	25,000
3,4-Methylenedioxymethamphetamine (MDMA)	50
l-Phenylephrine	4,000
Procaine	2,000
(1R,2S) - (-) Ephedrine	400
MARIJUANA (THC)	
11-nor-Δ^9-THC-9 COOH	12
Cannabinol	12,500
11-nor-Δ^8-THC-9 COOH	2
Δ^8-THC	6,000
Δ^9-THC	10,000
OPIATES (OPI)	
Morphine	40
Codeine	10
Ethylmorphine	24
Hydromorphone	100
Hydrocodone	100
Levorphanol	400
Oxycodone	25,000
Morphine 3-β-D-Glucuronide	50
Norcodeine	1,500
Normorphine	12,500
Nalorphine	10,000
Oxymorphone	25,000
Thebaine	1,500
Diacetylmorphine (Heroin)	50
6-Monoacetylmorphine (6-MAM)	25
Bilirubin	3,500
PHENCYCLIDINE (PCP)	
Phencyclidine	10
Tetrahydrozoline	50,000
OXYCODONE (OXY)	
Hydrocodone	6,250
Levorphanol	12,500
Naloxone	12,500
Naltrexone	6,250
Oxycodone	20
Secorbarbital	50,000
Oxymorphone	100
Hydromorphone	25,000

Cross-Reactivity

A study was conducted to determine the cross-reactivity of the test with compounds spiked into drug-free PBS stock. The following compounds demonstrated no false positive results on the **Alere *i*Screen® OFD Drug Test Device** when tested with concentrations up to 100 µg/mL.

Acetaminophen
N-Acetylprocainamide
Aminopyrine
Ampicillin
Apomorphine
Atropine
Benzoic acid
Bilirubin
Caffeine
Chloralhydrate
Chlorothiazide
Chlorpromazine
Cholesterol
Cortisone
Creatinine
Dextromethorphan
Diflunisal
Diphenhydramine
β-Estradiol
Ethyl-p-aminobenzoate
Erythromycin
Furosemide
Hemoglobin
Hydrochlorothiazide
o-Hydroxyhippuric acid
Ibuprofen
d,l-Isoproterenol
Ketamine
Labetalol
Meperidine
Methylphenidate
Naproxen
Nifedipine
d-Norpropoxyphene
d,l-Octopamine
Oxolinic acid
Papaverine
Pentazocine
Phenelzine
Phenylpropanolamine
Prednisone
d-Propoxyphene
Quinacrine
Quindine
Salicylic acid
Sulfamethazine
Tetracycline
Thiamine
d,l-Tyrosine
Triamterene
Trimethoprim
Tyramine
Verapamil
Acetophenetidin
Acetylsalicylic acid
Amoxicillin
l-Ascorbic acid
Aspartame
Benzilic acid
Benzphetamine
d,l-Brompheniramine
Cannabidol
Chloramphenicol
d,l-Chloropheniramine
Chloroquine
Clonidine
l-Cotinine
Deoxycorticosterone
Diclofenac
Digoxin
l-Ψ-Ephedrine
Estrone-3-sulfate
l-(-)-Epinephrine
Fenoprofen
Gentisic acid
Hydralazine
Hydrocortisone
p-Hydroxytyramine
Iproniazid
Isoxsuprine
Ketoprofen
Loperamide
Meprobamate
Nalidixic acid
Niacinamide
Norethindrone
Noscapine
Oxalic acid
Oxymetazoline
Penicillin-G
Perphenazine
Trans-2-phenylcyclopropylamine
Prednisolone
d,l-Propranolol
d-Pseudoephedrine
Quinine
Ranitidine
Serotonin
Sulindac
Tetrahydrocortisone 3-Acetate
Thioridazine
Tolbutamide
Trifluoperazine
d,l-Tryptophan
Uric acid
Zomepirac

BIBLIOGRAPHY

1. Moolchan, E., et al, “Saliva and Plasma Testing for Drugs of Abuse: Comparison of the Disposition and Pharmacological Effects of Cocaine”, Addiction Research Center, IRP, NIDA, NIH, Baltimore, MD. As presented at the SOFT-TIAFT meeting October 1998.
2. Kim, I, et al, “Plasma and oral fluid pharmacokinetics and pharmacodynamics after oral codeine administration”, *Clin Chem,* 2002 Sept.; 48 (9), pp 1486-96.
3. Schramm, W. et al, “Drugs of Abuse in Saliva: A Review,” *J Anal Tox*, 1992 Jan-Feb; 16 (1), pp 1-9.
4. McCarron, MM, et al, “Detection of Phencyclidine Usage by Radioimmunoassay of Saliva,” *J Anal Tox*. 1984 Sep-Oct.; 8 (5), pp 197-201.

Alere™

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OrALert™

Oral Fluid Drug Screen Device

Package Insert for the AMP/BZO/COC/THC/mAMP/OPI/PCP Test for Oral Fluids

A rapid, screening test for the simultaneous, qualitative detection of amphetamine, benzodiazepines, cocaine, marijuana, methamphetamine, opiates, and phencyclidine and their metabolites in human oral fluid.

For Forensic Use Only

INTENDED USE

The OrALert™ Oral Fluid Drug Screen Device for AMP/BZO/COC/THC/mAMP/OPI/PCP is a lateral flow chromatographic immunoassay for the qualitative detection of amphetamine, methamphetamine, cocaine, opiates, marijuana, phencyclidine, benzodiazepines and their metabolites in oral fluids at the following cut-off concentrations:

Test	Calibrator	Cut-off
Amphetamine (AMP)	d-Amphetamine	50 ng/mL
Benzodiazepines (BZO)	Oxazepam	20 ng/mL
Cocaine (COC)	Benzoylecgonine	20 ng/mL
Marijuana (THC)	Δ^9- THC	100 ng/mL
Methamphetamine (mAMP)	d-Methamphetamine	50 ng/mL
Opiates (OPI)	Morphine	40 ng/mL
Phencyclidine (PCP)	Phencyclidine	10 ng/mL

This assay provides only a preliminary analytical test result. A more specific alternate chemical method must be used in order to obtain a confirmed analytical result. Gas chromatography/mass spectrometry (GC/MS), gas chromatography/tandem mass spectrometry (GC/MS/MS) and liquid chromatography/tandem mass spectrometry (LC/MS/MS) are the preferred confirmatory methods. Professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are indicated.

SUMMARY

The OrALert™ Oral Fluid Drug Screen Device for AMP/BZO/COC/THC/mAMP/OPI/PCP and their metabolites is a rapid, oral fluid screening test that can be performed without the use of an instrument. The test utilizes monoclonal antibodies to selectively detect elevated levels of specific drugs in human oral fluid.

Amphetamine (AMP)

Amphetamine is a sympathomimetic amine with therapeutic indications. The drug is often self-administered by nasal inhalation or oral ingestion. Depending on the route of administration, amphetamine can be detected in oral fluid as early as 5-10 minutes following use.[1] Amphetamine can be detected in oral fluid for up to 72 hours after use.[1]

The Amphetamine assay contained within the OrALert™ Oral Fluid Drug Screen Device yields a positive result when the amphetamine concentration in oral fluid exceeds 50 ng/mL.

Benzodiazepines (BZO)

Benzodiazepines are medications that are frequently prescribed for the symptomatic treatment of anxiety and sleep disorders.

The Benzodiazepines assay contained within the OrALert™ Oral Fluid Drug Screen Device yields a positive result when the oxazepam concentration in oral fluid exceeds 20 ng/mL.

Cocaine (COC)

Cocaine is a potent CNS stimulant and a local anesthetic derived from the coca plant (erythroxylum coca). The drug is often self-administered by nasal inhalation, intravenous injection and free-base smoking. Depending on the route of administration, cocaine and its metabolites, benzoylecgonine and ecgonine methylester, can be detected in oral fluid as early as 5-10 minutes following use.[1] Cocaine and benzoylecgonine can be detected in oral fluid for up to 24 hours after use.[1]

The Cocaine assay contained within the OrALert™ Oral Fluid Drug Screen Device yields a positive result when the cocaine metabolite concentration in oral fluid exceeds 20 ng/mL.

Marijuana (THC)

Tetrahydrocannabinol (THC), the active ingredient in the marijuana plant (*cannabis sativa*), is detectable in oral fluid shortly after use. The detection of the drug is thought to be primarily due to the direct exposure of the drug to the mouth (oral and smoking administrations) and the subsequent sequestering of the drug in the buccal cavity.[3] Historical studies have shown a window of detection for THC in oral fluid of up to 14 hours after drug use.[3]

The THC assay contained within the OrALert™ Oral Fluid Drug Screen Device yields a positive result when the Δ^9-THC concentration in oral fluid exceeds 100 ng/mL.

Methamphetamine (mAMP)

Methamphetamine is a potent stimulant chemically related to amphetamine but with greater central nervous system (CNS) stimulation properties. The drug is often self-administered by nasal inhalation, smoking or oral ingestion. Depending on the route of administration, methamphetamine can be detected in oral fluid as early as 5-10 minutes following use.[1] Methamphetamine can be detected in oral fluid for up to 72 hours after use.[1]

The Methamphetamine assay contained within the OrALert™ Oral Fluid Drug Screen Device yields a positive result when the methamphetamine concentration in oral fluid exceeds 50 ng/mL.

Opiates (OPI)

The drug class opiates refers to any drug that is derived from the opium poppy, including naturally occurring compounds such as morphine and codeine and semi-synthetic drugs such as heroin. Opiates act to control pain by depressing the central nervous system. The drugs demonstrate addictive properties when used for sustained periods of time; symptoms of withdrawal may include sweating, shaking, nausea and irritability. Opiates can be taken orally or by injection routes including intravenous, intramuscular and subcutaneous; illegal users may also take the drug intravenously or by nasal inhalation. Using an immunoassay cutoff level of 40 ng/mL, codeine can be detected in the oral fluid within 1 hour following a single oral dose and can remain detectable for 7-21 hours after the dose.[2] 6-Monoacetylmorphine (6-MAM) is found more prevalently in oral fluid, and is a metabolic product of heroin. Morphine is a major metabolic product of codeine and heroin, and is detectable for 24-48 hours following an opiate dose.

The Opiates assay contained within the OrALert™ Oral Fluid Drug Screen Device yields a positive result when the morphine concentration in oral fluid exceeds 40 ng/mL.

Phencyclidine (PCP)

Phencyclidine (PCP), the hallucinogen commonly referred to as Angel Dust, can be detected in oral fluid as a result of the exchange of the drug between the circulatory system and the oral cavity. In a paired serum and oral fluid sample collection of 100 patients in a hospital emergency department, PCP was detected in the oral fluid of 79 patients at levels as low as 2 ng/mL and as high as 600 ng/mL.[4]

The Phencyclidine assay contained within the OrALert™ Oral Fluid Drug Screen Device yields a positive result when the PCP concentration in oral fluid exceeds 10 ng/mL.

ASSAY PRINCIPLE

The OrALert™ Oral Fluid Drug Screen Device for AMP/BZO/COC/THC/mAMP/OPI/PCP is an immunoassay based on the principle of competitive binding. Drugs that may be present in the oral fluid specimen compete against their respective drug conjugates for binding sites on their specific antibody.

During testing, a portion of the oral fluid specimen migrates upward by capillary action. A drug, if present in the oral fluid specimen below its cut-off concentration, will not saturate the binding sites of its specific antibody. The antibody will then react with the drug-protein conjugate and a visible colored line will show up in the test line region of the specific drug strip. The presence of drug above the cut-off concentration in the oral fluid specimen will saturate all the binding sites of the antibody. Therefore, the colored line will not form in the test line region.

A drug-positive oral fluid specimen will not generate a colored line in the specific test line region of the strip because of drug competition, while a drug-negative oral fluid specimen will generate a line in the test line region because of the absence of drug competition.

To serve as a procedural control, a colored line will always appear at the control line region, indicating that proper volume of specimen has been added and membrane wicking has occurred.

REAGENTS

The test contains membrane strips coated with drug-protein conjugates (purified bovine albumin) on the test line, a goat polyclonal antibody against gold-protein conjugate at the control line, and a dye pad which contains colloidal gold particles coated with mouse monoclonal antibody specific to Amphetamine, Oxazepam, Benzoylecgonine, Δ^9- THC, Methamphetamine, Morphine, and Phencyclidine.

PRECAUTIONS

- **For forensic use only**.
- Do not use after the expiration date.
- The Oral Fluid test device should remain in the sealed pouch until use.
- Saliva is not classified as biological hazard unless derived from a dental procedure.
- The used collector and device should be discarded according to federal, state and local regulations.

STORAGE AND STABILITY

Store as packaged in the sealed pouch at 2-30°C. The test is stable through the expiration date printed on the sealed pouch. The test devices must remain in the sealed pouch until use. DO NOT FREEZE. Do not use beyond the expiration date.

SPECIMEN COLLECTION AND PREPARATION

The oral fluid specimen should be collected using the collector provided with the kit, following the detailed instructions under Directions for Use. No other collection devices should be used with this assay. Oral fluid collected at any time of the day may be used.

MATERIALS

Materials Provided

- Test devices
- Caps
- Collectors
- Procedure cards
- Tamper evident tape
- Package insert

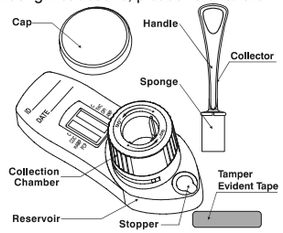
Materials Required but not Provided

- Timer

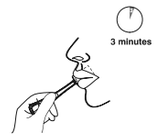
DIRECTIONS FOR USE

Allow the OrALert™ Oral Fluid Drug Screen Device to come to room temperature [15-30°C (59-86°F)] prior to testing. Instruct the donor to not place anything in the mouth including food, drink, gum, or tobacco products for at least 10 minutes prior to collection.

1. Bring the pouch to room temperature before opening it. Remove the test and cap from the sealed pouch and use the test as soon as possible.
2. Remove the collector from the sealed pouch and give it to the donor.
3. Instruct the donor to insert the sponge end of the collector into the mouth and actively swab the inside of the mouth and the top of the tongue. As soon as the sponge softens slightly, the donor should gently press the sponge between the tongue and teeth to ensure complete saturation.
4. The sponge is saturated when no hard spots can be detected. Collect for a total of three (3) minutes before removing the sponge.
5. Remove the collector from the mouth. With the test device on a flat surface, insert the collector into the test device by aligning the notches on the collector with the tracks on the inside of the collection chamber. Push the collector into the chamber and turn the collector clockwise until it is engaged.
6. After 1 minute, rotate the collection chamber counterclockwise and set the timer for 9 minutes.
7. Read results at 9 minutes.
8. If positive results are observed, remove the collector by turning it counterclockwise and pulling. Secure the cap over the collection chamber, seal the reservoir with tamper evident tape and send the device to a laboratory for confirmation. The laboratory can access the reservoir through the stopper.
9. For detailed operating instructions, please refer to the Procedure Card.



Step 1 and 2



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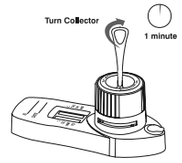

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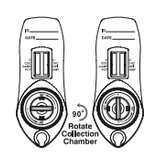

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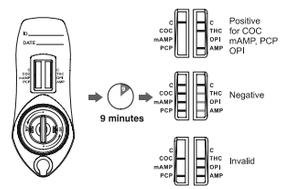

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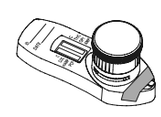

Step 8

INTERPRETATION OF RESULTS

(Please refer to the previous illustration)

NEGATIVE:* Two lines appear. One colored line should be in the control region (C), and another apparent colored line should be adjacent in the test region (Drug/T). This negative result indicates that the drug concentration is below the detectable level.

***NOTE**: The shade of color in the test region (Drug/T) will vary, but it should be considered negative whenever there is even a faint colored line.

POSITIVE: One colored line appears in the control region (C). No line appears in the test region (Drug/T). This positive result indicates that the drug concentration is above the detectable level.

INVALID: Control line fails to appear. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test using a new test panel. If the problem persists, discontinue using the lot immediately and contact the manufacturer.

QUALITY CONTROL

A procedural control is included in the test. A colored line appearing in the control region (C) is considered an internal procedural control. It confirms sufficient specimen volume, adequate membrane wicking and correct procedural technique.

LIMITATIONS

1. The OrALert™ Oral Fluid Drug Screen Device provides only a qualitative, preliminary analytical result. A secondary analytical method must be used to obtain a confirmed result. Gas chromatography/mass spectrometry (GC/MS), gas chromatography/tandem mass spectrometry (GC/MS/MS) or liquid chromatography/tandem mass spectrometry (LC/MS/MS) are preferred confirmatory methods.
2. A positive test result does not indicate the concentration of drug in the specimen or the route of administration.
3. A negative result may not necessarily indicate a drug-free specimen. Drug may be present in the specimen below the cutoff level of the assay.

PERFORMANCE CHARACTERISTICS

Analytical Sensitivity

A PBS pool was spiked with drugs to target concentrations of ± 50% cut-off and ± 25% cut-off and tested with the OrALert™ Oral Fluid Drug Screen Device. The results are summarized below.

Drug conc. (Cut-off range)	AMP		BZO		COC		THC	
	-	+	-	+	-	+	-	+
0% Cut-off	120	0	87	0	90	0	120	0
-50% Cut-off	120	0	87	0	90	0	120	0
-25% Cut-off	109	11	85	2	90	0	108	12
Cut-off	60	60	67	20	45	45	60	60
+25% Cut-off	10	110	36	51	0	90	12	108
+50% Cut-off	0	120	17	70	0	90	3	117

Drug conc. (Cut-off range)	mAMP		OPI		PCP	
	-	+	-	+	-	+
0% Cut-off	90	0	120	0	90	0
-50% Cut-off	90	0	120	0	90	0
-25% Cut-off	90	0	108	12	89	1
Cut-off	45	45	60	60	63	27
+25% Cut-off	0	90	10	110	23	67
+50% Cut-off	0	90	0	120	0	90

Analytical Specificity

The following table lists the concentration of compounds (ng/mL) above which the OrALert™ Oral Fluid Drug Screen Device for AMP/BZO/COC/THC/mAMP/OPI/PCP identified positive results at a read time of 10 minutes.

AMPHETAMINE (AMP)	
d-Amphetamine	50
d,l-Amphetamine	125
l-Amphetamine	4,000
p-Hydroxyamphetamine	800
(+) 3,4-Methylenedioxyamphetamine (MDA)	150
β-Phenylethylamine	4,000
Tryptamine	1,500
BENZODIAZEPINES (BZO)	
Oxazepam	20
Alprazolam	6
Bromazepam	12
Chlordiazepoxide	12
Clobazam	6
Clorazepate	25
Delorazepam	25
Desalkylflurazepam	25
Diazepam	3
Estazolam	3
Flunitrazepam	100
α-Hydroxyalprazolam	200
(±)-Lorazepam	200
Midazolam	25
Nitrazepam	12
Norchlordiazepoxide	200
Nordiazepam	25
Temazepam	6
Triazolam	25
COCAINE (COC)	
Benzoylecgonine	20
Cocaine	20
Cocaethylene	25
Ecgonine	1,500
Ecgonine methylester	12,500
MARIJUANA (THC)	
Δ^9–THC	100
Δ^8–THC	100
11-nor-Δ^9- THC -9 COOH	12
Cannabinol	3,000
METHAMPHETAMINE (mAMP)	
Methamphetamine	50
Ephedrine	800
(1R,2S)-(-)-Ephedrine	400
l-Ephedrine	20,000
Fenfluramine	60,000
p-Hydroxymethamphetamine	400
Mephentermine	800
L-Methamphetamine	3,000
Methoxyphenamine	25,000
(+)3,4-Methylendioxy-methamphetamine (MDMA)	50
l-Phenylephrine	4,000
Procaine	2,000
OPIATES (OPI)	
Morphine	40
Bilirubin	3,500
Codeine	10
Diacetylmorphine (Heroin)	50
Ethylmorphine	24
Hydromorphone	100
Hydrocodone	100
Levorphanol	400
6-Monoacetylmorphine (6-MAM)	25
Morphine 3-β-D-glucuronide	50
Norcodeine	1,500
Normorphine	12,500
Nalorphine	10,000
Oxycodone	25,000
Oxymorphone	25,000
Thebaine	1,500
PHENCYCLIDINE (PCP)	
Phencyclidine	10
Tetrahydrozoline	50,000

Cross-Reactivity

A study was conducted to determine the cross-reactivity of the test with compounds spiked into drug-free PBS stock. The following compounds demonstrated no false positive results on the OrALert™ Oral Fluid Drug Screen Device when tested with concentrations up to 100 µg/mL.

4-Acetamidophenol	Diclofenac	Ketoprofen	Prednisone
Acetone	Dicyclomine	Labetalol	Procyclidine
N-Acetylprocainamide	Diflunisal	Lidocaine	Promazine
Acetylsalicylic acid	Digoxin	Lindane	Promethazine
Albumin	4-Dimethylaminoantipyrine	Lithium	d,l-Propanolol
Aminopyrine	Diphenhydramine	Loperamide	d-Propoxyphene
Amitriptyline	EDDP	Maprotiline	Quinine
Amobarbital	EMDP	Meperidine	R (-)Deprenyl
Amoxapine	l-Epinephrine	Meprobamate	Riboflavin
Amoxicillin	Erythromycin	Methaqualone	Salicylic acid
Ampicillin	β-Estradiol	Methylphenidate	Seroquel
Apomorphine	Ethyl alcohol	Metoprolol	Serotonin
Ascorbic acid	Etodolac	Nalidixic acid	Sertraline
Aspartame	Famprofazone	Naproxen	Sodium chloride
Barbital	Fenoprofen	Niacinamide	Sulfamethazine
Benzilic acid	Fentanyl	Nimesulide	Sulindac
Benzoic acid	Fluoxetine	Norethindrone	Tetracycline
Brompheniramine	Furosemide	d-Norpropoxyphene	Theophylline
Buprenorphine	Gentisic acid	Noscapine	Thiamine
Buspirone	d-Glucose	d,l-Octopamine	Thioridazine
Caffeine	Guaiacol Glyceryl Ether	Orphenadrine	l-Thyroxine
Chloral hydrate	Hemoglobin	Oxalic acid	Tolbutamide
Chloramphenicol	Hydralazine	Oxolinic acid	Trans-2-Phenylcyclopropylamine
Chloroquine	Hydrochlorothiazide	Oxymetazoline	Trazodone
Chlorothiazide	Hydrocortisone	Papaverine	Triamterene
Chlorpromazine	3-Hydroxytyramine	Pemoline	Trifluoperazine
Chlorprothixene	o-Hydroxyhippuric acid	Penicillin	Trimethobenzamide
Cimetidine	Ibuprofen	Pentazocine	Trimipramine
Cis-Tramadol	Imipramine	Pentobarbital	d,l-Tryptophan
Clomipramine	Iproniazide	Phenelzine	d,l-Tyrosine
Clonidine	Isoproterenol	Phenobarbital	Uric acid
Creatinine	Isoxsuprine	Phenothiazine	Verapamil
Deoxycorticosterone	Kanamycin	Phentermine	Zomepirac
Dextromethorphan	Ketamine	Prednisolone	

BIBLIOGRAPHY

1. Moolchan, E., et al, “Saliva and Plasma Testing for Drugs of Abuse: Comparison of the Disposition and Pharmacological Effects of Cocaine”, Addiction Research Center, IRP, NIDA, NIH, Baltimore, MD. As presented at the SOFT-TIAFT meeting October 1998.
2. Kim, I, et al, “Plasma and oral fluid pharmacokinetics and pharmacodynamics after oral codeine administration”, *Clin Chem,* 2002 Sept.; 48 (9), pp 1486-96.
3. Schramm, W. et al, “Drugs of Abuse in Saliva: A Review,” *J Anal Tox*, 1992 Jan-Feb; 16 (1), pp 1-9.
4. McCarron, MM, et al, “Detection of Phencyclidine Usage by Radioimmunoassay of Saliva,” *J Anal Tox*. 1984 Sep-Oct.; 8 (5), pp 197-201.

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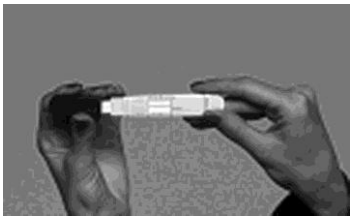
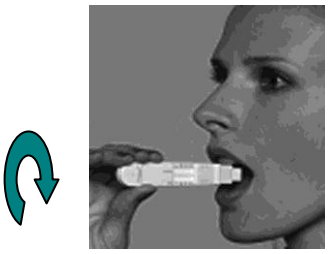
Oratect® Quick Reference Guide

The Alere Oratect® Oral Fluid Drug Screen Device is a simple one-step test for the detection of drugs of abuse in oral fluid.

1. **Remove** the cranberry color cap by holding the sides and pulling gently. This will expose the collection pad. **Make sure there is a blue line present in each window area indicating an unused device.**



2. **Open** mouth and gently **rub** the collection pad inside mouth against cheek in a circular motion several (approximately 15-20) times. Make sure to **keep head level.**

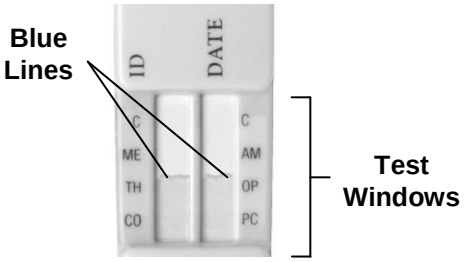


3. Gently **rub** the collection pad against the opposite cheek in circular motion several (approximately 15-20) times.

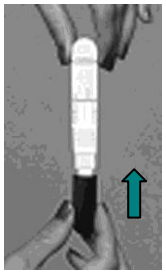
4. Gently **rub** the collection pad **on top** of the tongue several (approximately 15-20) times. **Do not chew, suck, bite or bend the collection pad.**

5. **Rub** the collection pad **underneath** the tongue several (approximately 15-20) times.

6. Place the collection pad underneath the tongue for approximately 30 seconds to collect saliva. Instruct the donor to hold the device in place with hand. **When sufficient amount of saliva is collected the blue lines will move. Repeat steps 2-6 until blue lines start to move upward**



7. **Remove** from mouth as soon as blue lines move in both of the test windows. **Re-cap** the device.



8. Lay the device on a flat surface and **read results in approximately 5 minutes after removing the device from mouth. Read package insert.**

Interpreting Test Results

Invalid Result

When **no** colored band appears in the **CONTROL (C) region**, **the test is invalid** even if there is a band in the test region. **Repeat** the test with a new device.

Example Interpretation:

ME: Invalid
TH: Invalid
CO: Invalid
AM: Invalid
OP: Invalid
PC: Invalid

Negative Result

For each test, two colored bands should be observed:

- **One in the CONTROL (C) region**
- **One in the specific TEST region**

The color of the test band may be slightly darker or lighter than the control band. Any visible band that can be seen is a **negative** result.

Example Interpretation:

ME: Negative
TH: Negative
CO: Negative
AM: Negative
OP: Negative
PC: Negative

Presumptive Positive Result

A colored band at the CONTROL (C) region should be observed. When there is no colored band or shadow band at the specific **TEST region**, the test is presumptive positive for that particular drug.

Example Interpretation:

ME: **Presumptive Positive**
TH: Negative
CO: Negative
AM: Negative
OP: Negative
PC: Negative

Alere Oratect®
Oral Fluid Drug Screen Device

Catalog number: AOT-06

The Alere Oratect® Oral Fluid Drug Screen Device is a one-step lateral flow immunoassay device for the qualitative detection of Methamphetamine (ME), Marijuana (TH), Cocaine (CO), Amphetamine (AM), Opiate (OP) and Phencyclidine (PC) in human oral fluid. The Alere Oratect® Test detects these drugs at the cut-off concentration listed below and their metabolites. The test is a prescription assay. This product is for *in vitro* diagnostic use and it can be used at the Point-of-Care site.

The Alere Oratect® Test device detects these drugs at the following cut-off concentrations:

Test	Calibrator	Cut-off
Methamphetamine (ME)	d-Methamphetamine	50 ng/mL
Marijuana (TH)	Delta-9-Tetrahydrocannabinol	40 ng/mL
Cocaine (CO)	Cocaine	20 ng/mL
Amphetamine (AM)	d-Amphetamine	50 ng/mL
Opiate (OP)	Morphine	40 ng/mL
Phencyclidine (PC)	Phencyclidine	10 ng/mL

The Alere Oratect® Oral Fluid Drug Screen Device provides only preliminary drug test results. For a quantitative result or for a confirmation of a presumptive positive result obtained by the Alere Oratect® Oral Fluid Drug Screen Device, a more specific alternative method must be used. GC/MS or LC/MS/MS is the preferred confirmatory method. The samples for confirmatory testing should be collected with the oral fluid confirmation tube provided.

Summary and Explanation

Illegal drug consumption contributes to many accidents, injuries and medical conditions. Screening individuals for drugs of abuse is an important method in identifying those who may cause harm to themselves and to others.

The Alere Oratect® Oral Fluid Drug Screen Device is developed to detect active drugs-of-abuse present in saliva. Studies on methamphetamine, cannabinoid, cocaine, amphetamine, opiates, and phencyclidine show that all of these drugs are detectable in oral fluids[5]. The Alere Oratect® Oral Fluid Drug Screen Device is designed to integrate oral fluid collection and lateral flow immunoassay screen testing for drugs-of-abuse in one single device.

Test Principle

The Alere Oratect® Oral Fluid Drug Screen Device is based on a competitive immunoassay procedure in which drug derivatives immobilized on the membrane compete with the drug(s) which may be present in oral fluid for limited antibody binding sites on the colored colloidal gold antibody conjugate. During testing, oral fluid is collected at the collection pad and migrates across the membrane. If no drug is present in the oral fluid, the colored colloidal gold antibody conjugate will bind to the drug derivatives on the membrane to form visible bands at specific test regions. Therefore, the **presence of a purple-red band** at a specific test region indicates a **negative result**. If any drug(s) is (are) present in the oral fluid, it competes with the immobilized drug conjugate for limited antibody binding sites of the colored colloidal gold conjugate. When a sufficient amount of drug is present, the drug will saturate the antibodies, and the colored colloidal gold conjugate cannot bind to the drug derivative on the membrane. **Therefore, the absence of a purple-red band at the test region indicates a presumptive positive result for that particular test.**

Fig a

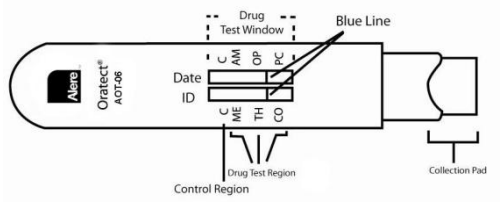


Fig. a Detail regions of the Alere Oratect® Oral Fluid Drug Screen Device. Note: This is a representative drawing detail for catalogue number AOT-06.

The presence of a blue line in each window indicates that the device is unused. The movement of the blue lines indicates that a sufficient amount of oral fluid has been collected. A control band at the control region (C) indicates the test has performed properly. This control band should always appear regardless of the presence of drug or metabolite.

Reagents

The Alere Oratect® Oral Fluid Drug Screen Device contains one or two membrane strips and a collection pad. Each strip consists of a membrane, a colloidal gold conjugate pad, a sample pad and an absorbent pad.
The number of drugs per strip may vary depending on the selected product catalogue number.

Membrane:
ME/TH/CO test strip: Methamphetamine, THC and Cocaine-protein conjugates are coated onto specific region on the membrane known as the "Test Region".

AM/OP/PC test strip: Amphetamine, Opiate, Phencyclidine protein conjugates are coated onto the test region of the membrane.

Colloidal Gold Conjugate Pad: The colloidal gold conjugate pad for the ME/TH/CO test strip contains mouse monoclonal anti-methamphetamine, anti-THC and anti-cocaine antibody colloidal gold conjugates coated onto a fibrous pad. The colloidal gold conjugate pad for the AM/OP/PC test strip contains mouse monoclonal anti-amphetamine, anti-morphine, anti-phencyclidine antibody colloidal gold conjugates.

Collection Pad: The collection pad consists of an absorbent material.

Materials Provided

Each Oratect® Oral Fluid Drug Screen Device kit contains:

- 25 test devices. Each device consists of a plastic holder and a detachable cap. The devices are packaged individually in a foil pouch with a desiccant.
- 1 Package Insert
- 2 Oral Fluid Collection Tubes (50 mL polypropylene tube) for confirmation shipping. The Alere Oratect® Oral Fluid Collection Tubes provided in this kit should only be used for the confirmation sample.

Warnings and Precautions

- For *in vitro* diagnostic use only
- The test device should remain in its original sealed pouch until ready for use.
- Discard the test device if package is ripped or torn.
- Do not use the test device beyond the expiration date indicated on the kit.
- Handle all oral specimens as potentially infectious. Proper handling and disposal methods should be established.

Product Storage

The Alere Oratect® Oral Fluid Drug Screen Device pouch should be stored at room temperature 15°-30°C (59°-86°F). Do not open pouch until ready to perform the assay.

Specimen Collection and Handling

IMPORTANT: At least 10 minutes prior to administering the test, instruct the donor not to eat, drink, smoke or chew tobacco products.

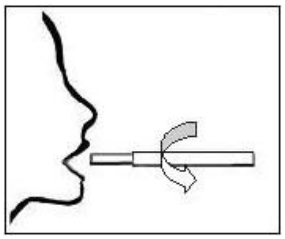
Presumptive positive samples are collected in the 50 ml collection tube supplied and mailed immediately to confirm the test.

Confirmation laboratory may keep samples for up to 2 weeks when stored at 2 – 8 °C or up to 24 months when stored below -15°C.

Test Procedure

1. Remove the test device from the sealed pouch.
2. Carefully remove the cranberry color cap by holding the sides and pull gently. This will expose the collection pad.
3. Ensure that the blue line is present in each test window.
4. The oral fluid collection process must be observed. Instruct the donor to hold the top portion of the device (above the test windows).
5. When placing device into the mouth, **keep head level**.
   a. Open mouth and rub the collection pad inside mouth against one cheek gently in a circular motion several (approximately 15-20) times. **(Fig. b)**
   b. Still keeping head level, gently rub the collection pad against the opposite cheek in a circular motion (approximately 15-20) several times. **(Fig. b)**

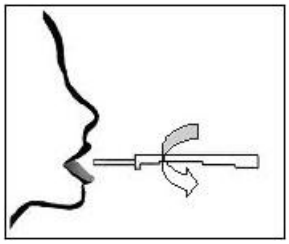
Fig b



Gently rub the collection pad against each cheek several (approximately 15-20) times.

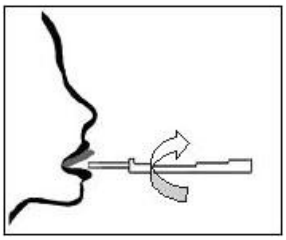
c. Rub the collection pad on top of the tongue several times and then underneath the tongue several (approximately 15-20) times.
(Fig c. and Fig d.). Do not chew, suck, bite or bend the collection pad.

Fig c



Gently rub the collection pad on top of the tongue several (approximately 15-20) times.

Fig d



Gently rub the collection pad underneath the tongue several (approximately 15-20) times.

6. Place the collection pad underneath the tongue for approximately 30 seconds to collect saliva. Instruct the donor to hold the device in place with their hand.
7. The movement of the blue lines indicates the collection of a sufficient amount of saliva has occurred. If blue lines are still stationary after placing the collection pad underneath the tongue for 30 seconds, repeat the procedure in steps 5 and 6 until the blue lines move.
8. Remove the device from mouth as soon as the blue lines start moving at both test windows.

   Note: The flow of the blue lines should appear in the test windows within 5 minutes. If no flow is observed after 5 minutes in the mouth, discard the device, review procedures 4-7 above with the donor and repeat the test using a new device.
9. Re-cap the device, lay it on a flat surface and **read results in approximately 5 minutes after removing device from mouth. Do not read results after 15 minutes.**

Interpreting Test Results

Negative Results

For each of the test windows, purple-red colored bands should be observed; one band at the control region (C) and one band at the specific drug abbreviation (e.g. AM, OP, CO) in the test region. See example Fig e.

The color of the test band may be slightly darker or lighter than the control band. Any band that can be seen visually, no matter how faint, is a **negative** result. Read each test independently. Do not compare color intensity of one test to another.

In the **Fig. e** below, the oral fluid sample is negative for Amphetamine, Opiate and Cocaine **because bands are visible in the AM, OP, and CO test regions**.

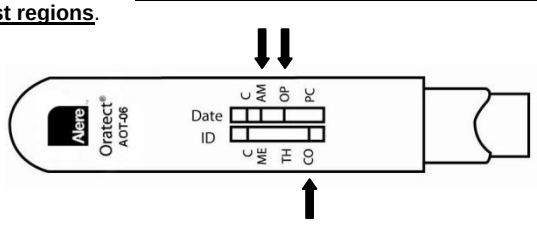


Fig e. Example of Negative Test Results

Presumptive Positive Results

When the control band is visible in the control region (C) and **no** band or shadow band appears at the specific test region, the result is a **presumptive positive** for that particular drug. In **Fig. f** below, the oral fluid sample is presumptive positive for Phencyclidine, Methamphetamine and THC **because no bands are visible in the test regions of PC, ME, and TH.**

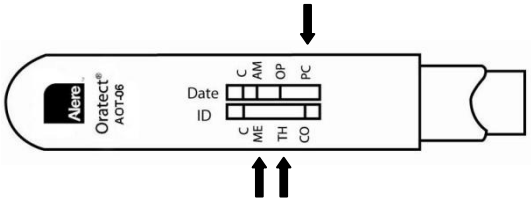


Fig. f Example of Presumptive Positive Test Results

Invalid Results

When **no** band appears in the control (C) region, **the test is invalid** regardless of the results in the test region. If the test is invalid, check testing procedures. **Repeat the test using a new device.** In **Fig. g** below, the test is invalid because there are **no bands in the control regions.**

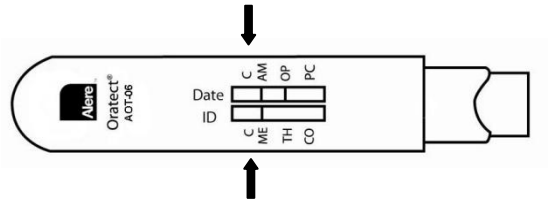


Fig. g Example of Invalid Test Results

Important: Read each test independently. Do not compare color intensity of one test band to another. When a faint purple-red band for a specific test is obtained in the test region along with the presence of the control line (C), the sample should be considered negative. The Alere Oratect® Oral Fluid Drug Screen Device only provides qualitative results for the presence of drug(s) at specified cut-off concentration(s). For confirmation of a presumptive positive result, a more specific method (GC/MS or LC/MS/MS) must be used.

Instructions for collecting a confirmation oral fluid sample.

1. If a user of this product obtains a presumptive positive test result, the user should obtain confirmation testing using a more specific test method such as Gas Chromatography/Mass Spectrometry (GC/MS) or Liquid Chromatography/Mass Spectrometry (LC/MS/MS). The test sample for this confirmation testing should be collected immediately after obtaining the presumptive positive test result(s).
2. Use only the Alere Oratect® Oral Fluid Collection Tube (50ml polypropylene tube) provided in this kit. Note: If additional sample collection tubes are needed, please contact Alere Toxicology customer service at 1-800-340-4029. Remove cap from collection tube and carefully spit into tube several times until half of the bottom cone (~ 2.5 mLs) is collected.
3. Tightly re-cap sample collection tube.
4. Complete the tube label affixed to sample collection tube with the requested information.
5. Avoid high temperatures and sunlight pending shipment.
6. Mail the sample immediately to a license test laboratory for GC/MS or LC/MS/MS confirmation testing. The sample should be shipped by an overnight courier service using a small shipping box or padded envelope.

Quality Control

Internal control: The Alere Oratect® Oral Fluid Drug Screen Device provides a built-in control bands in each window at the control regions (C) to indicate that the test has performed properly. These control bands should always appear regardless of the presence of drugs. The flow of the blue lines indicates that a sufficient amount of oral fluid has been collected. The presence of the purple-red bands in the control regions verifies that proper flow was obtained. If the control bands do not appear, the test device should be discarded.

External control: It is recommended that negative and positive saliva controls be used to initially test each new lot of product to ensure proper kit performance. The use of the Alere Oratect® Oral Fluid Drug Screen Device Controls under catalogue number OC001 may be used

as external quality control material. The pipette test procedure provided with the Alere Oratect® Oral Fluid Drug Screen Device Controls package insert should be followed. Each Laboratory should establish and run its own QC program as it is familiar with its own environment. When external controls do not produce the expected results, repeat with a new unopened bottle of controls.

Quality control testing at regular intervals is a good laboratory practice and laboratories should comply with all federal, state, and local laws, guidelines and regulations. Always check with the appropriate licensing or accrediting bodies to ensure that the quality program employed meets the established standards.

Limitations of Procedure

- The assay is designed for human oral fluid use only.
- Positive results only indicate the presumptive presence of drugs and do not indicate or measure intoxication.
- Technical or procedural errors as well as substances in certain foods and certain medications may interfere with the test and cause false results.
- Do not use the device past expiration date
- Read instructions before testing
- Subjects with dry mouth symptoms have difficulty with this test

Performance Characteristics Comparison and Accuracy

The accuracy of the Alere Oratect® Oral Fluid Drug Screen Device was evaluated by testing Oratect product with clinical saliva samples which were subsequently analyzed by GC/MS or LC/MS/MS method. A minimum of forty negative samples and forty positive samples were tested. Of the forty positive samples, at least 4 samples were near negative (between 50% to 100%) and 4 samples were near positive (between 100% to 150%). The results are summarized below:

Drug Name		GC/MS negative	GC/MS negative <50%	Near cutoff negative ≥50% to <100%	Near cutoff positive ≥100% to <150%	GC/MS positive ≥150%	% Agree-ment with GC/MS
ME	+	0	0	5	3	58	97.5%
	-	180	9	9	1	0	98.4%
TH	+	0	0	10	7	36	100%
	-	185	20	7	0	0	95.5%
CO	+	0	0	3	5	38	100%
	-	210	6	3	0	0	98.6%
AM	+	0	0	7	12	34	100%
	-	170	38	4	0	0	96.8%
OP	+	0	0	4	3	55	96.7%
	-	186	12	3	2	0	98.0%
PC	+	0	0	1	2	38	95.2%
	-	223	1	5	2	0	99.6%

Precision

For each specific drug test, pooled oral fluid solution was spiked with a drug standard at various concentrations (0%, 25%, 50%, 75%, 100%, 125%, 150%, 175% and 200%). Three lots were tested by at least 3 operators at 3 different sites to validate the test performance. The results for each drug of the Alere Oratect® Oral Fluid Drug Screen Device Tests are summarized below:

Cut-off level	Drug Test											
	ME		TH		CO		AM		OP		PC	
	-	+	-	+	-	+	-	+	-	+	-	+
0%	360	0	360	0	360	0	360	0	360	0	360	0
25%	45	0	45	0	45	0	45	0	45	0	45	0
50%	45	0	45	0	45	0	45	0	45	0	45	0
75%	43	2	42	3	43	2	41	4	43	2	41	4
100%	26	19	25	20	27	18	22	23	23	22	25	20
125%	3	42	2	43	4	41	1	44	1	44	1	44
150%	0	45	0	45	0	45	0	45	0	45	0	45
175%	0	45	0	45	0	45	0	45	0	45	0	45
200%	0	45	0	45	0	45	0	45	0	45	0	45

Specificity

The specificity study for each drug test was evaluated by adding structurally related compounds to pooled oral fluid sample. The results are expressed as the amount of the compound, in ng/ml, that produced a positive result.

Drug Test	Approximate Concentration (ng/ml)	Approximate % Cross Reactivity
ME		
d-Methamphetamine	50	100%
d,l-Ephedrine	10,000	0.5%
1R, 2S l-Ephedrine	6,000	0.8%
p-Hydroxymethamphetamine	1,500	3.3%
MDEA	1,500	3.3%
MDMA	150	33.3%
d,l-Methamphetamine	60	83.3%
l-Methamphetamine	3,000	1.7%
Methoxyphenamine	10,000	0.5%
TH		
Δ-9-Tetrahydrocannabinol	40	100%
Cannabinol	100	40%
Δ-8-Tetrahydrocannabinol	100	40%
11-nor-Δ-8-THC-9-COOH	20	200%
11-nor-Δ-9-THC-9-COOH	10	400%
11-Hydroxy-Δ9-THC	400	10%
CO		
Cocaine	20	100%
Benzoylecgonine	600	3.3%
AM		
d-Amphetamine	50	100%
l-Amphetamine	2,000	2.5%
d,l-p-Chloramphetamine	400	12.5%
MDA	400	12.5%
Phentermine	100	50%
β-Phenylethylamine	10,000	0.5%
Tyramine	10,000	0.5%
OP		
Morphine	40	100%
6-Acetylcodeine	40	100%
6-Acetylmorphine	50	80%
Codeine	40	100%
Dihydrocodeine	200	20%
Ethyl morphine	75	53.3%
Heroin	40	100%
Hydrocodone	200	20%
Hydromophone	300	13.3%
Nalorphine	1,000	4%
PC		
Phencyclidine	10	100%
Dextromethorphan	>10,000	<0.1%
Doxylamine	>10,000	<0.1%
4-Hydroxy-Phencyclidine	50	20%
Ketamine	>10,000	<0.1%
Metaphit	125	8%
Phencyclidine Morpholine	750	1.3%

Interference

The Alere Oratect® Oral Fluid Drug Screen Test performance at ± 50% cut-off levels is not affected by any oral fluid samples with pH range of 4.0 to 8.5.

The following compounds were spiked into ± 50% oral fluid controls and found not to cross-react with the Alere Oratect® Oral Fluid Drug Screen Device when tested at concentration of 10 µg/ml (10,000ng/ml).

Acetaminophen	Hemoglobin
α-Amylase	Human IgA
Albumin from human serum	Human IgG
l-Ascorbic Acid	Human IgM
Aspartame	Ibuprofen
Benzillic acid	Ketamine
Benzocaine	Lidocaine
Benzoic acid	Meperidine
Bilirubin	Naloxone
Butethal	Naltrexone hydrochloride
Caffeine	d-Naproxen
d-Chlorpheniramine	Papaverine
Cholesterol	Pentazocine
Dextromethorphan	Promazine
Diphenhydramine	Promethazine
Doxylamine	Ranitidine
1R, 2S l- Ephedrine *(except ME assay)*	Riboflavin
	Salicylic acid
1S, 2R d-Ephedrine	Serotonin
l-Epinephrine	Tetracycline
Erythromycin	Thiamine
Ethanol	Tryptamine
Glutethimide	d,l-Tryptophan

Food/Beverage/Hygiene Products Interference

Foods, drinks and hygiene products were spiked at 1% concentration in ±25% and ±50% oral fluid controls to evaluate the interference with Oratect® test results. For interference of cigarette, oral fluid samples were collected from 6 subjects within 15 minutes after consuming a cigarette and then spiked with drug standards (MET, THC, COC, AMP, OPI, and PCP). The following substances were found not to interfere with Alere Oratect® Oral Fluid Drug Screen Test performance.

Mouth wash	Orange juice	Alcohol
MSG	Sugar	Cranberry juice
Salt	Food color: Red	Carbonated Cola
Toothpaste	Food color: Green	Baking Soda
Gum	Food color: Blue	Cigarette
Cough Syrup	Tea	

Bibliography of Suggested Reading

1. Wong, R. The Current Status of Drug Testing in the US Workforce, American Clinical Laboratory, vol. 21(1), page 21-23, 2002.
2. Caplan, Y. and Goldberger, B., Alternative Specimens for Workplace Drug Testing, J. Analytical Toxicology, vol. 25, p. 396-399, 2001.
3. Schramm, W., Smith, R. and Craig, P., Drugs of Abuse in Saliva: A Review, J. Analytical Toxicology, vol. 16, p. 1-9, 1992.
4. Mandatory Guidelines for Federal Workplace Drug Testing Programs, April 13, 2004 (69 FR 19644).
5. Wong, R. On-site Oral Fluid Drug Testing by Oratect, in Drugs of Abuse: Body Fluid Testing, Wong, R and Tse, H ed., Humana Press, p146-158, 2005.

Manufactured for: **Alere Toxicology Services – Products Division**
Portsmouth, VA 23704 USA
Phone: 1-800.340.4029
Fax: 1-888.340.4029
Web: www.aleretoxicology.com

Part No.: PI-X11-AOT-06 Rev: C, 10/2014

COT

One Step
Cotinine Test Device
Package Insert

A rapid, one step test for the qualitative detection of Cotinine (nicotine metabolite) in human urine.
For Determination of Smoking Status Only.

INTENDED USE

The COT One Step Cotinine Test Device (Urine) is a lateral flow chromatographic immunoassay for the detection of Cotinine in human urine at a cut-off concentration of 200 ng/mL. This test will detect other related compounds, please refer to the Analytical Specificity table in this package insert.

This assay provides only a preliminary analytical test result. A more specific alternate chemical method must be used in order to obtain a confirmed analytical result. Gas chromatography and mass spectrometry (GC/MS) is the preferred confirmatory method. Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are used.

SUMMARY

Cotinine is the first-stage metabolite of nicotine, a toxic alkaloid that produces stimulation of the autonomic ganglia and central nervous system when in humans. Nicotine is a drug to which virtually every member of a tobacco-smoking society is exposed whether through direct contact or second-hand inhalation. In addition to tobacco, nicotine is also commercially available as the active ingredient in smoking replacement therapies such as nicotine gum, transdermal patches and nasal sprays.

In a 24-hour urine, approximately 5% of a nicotine dose is excreted as unchanged drug with 10% as cotinine and 35% as hydroxycotinine; the concentrations of other metabolites are believed to account for less than 5%.[1] While cotinine is thought to be an inactive metabolite, it's elimination profile is more stable than that of nicotine which is largely urine pH dependent. As a result, cotinine is considered a good biological marker for determining nicotine use. The plasma half-life of nicotine is approximately 60 minutes following inhalation or parenteral administration.[2] Nicotine and cotinine are rapidly eliminated by the kidney; the window of detection for cotinine in urine at a cutoff level of 200 ng/mL is expected to be up to 2-3 days after nicotine use.

The COT One Step Cotinine Test Device (Urine) is a rapid urine screening test that can be performed without the use of an instrument. The test utilizes a monoclonal antibody to selectively detect elevated levels of Cotinine in urine. The COT One Step Cotinine Test Device (Urine) yields a positive result when the Cotinine in urine exceeds 200 ng/mL.

PRINCIPLE

The COT One Step Cotinine Test Device (Urine) is an immunoassay based on the principle of competitive binding. Drugs which may be present in the urine specimen compete against the drug conjugate for binding sites on the antibody.

During testing, a urine specimen migrates upward by capillary action. Cotinine, if present in the urine specimen below 200 ng/mL, will not saturate the binding sites of antibody coated particles in the test device. The antibody coated particles will then be captured by immobilized Cotinine conjugate and a visible colored line will show up in the test line region. The colored line will not form in the test line region if the Cotinine level exceeds 200 ng/mL because it will saturate all the binding sites of anti-Cotinine antibodies.

A drug-positive urine specimen will not generate a colored line in the test line region because of drug competition, while a drug-negative urine specimen or a specimen containing a drug concentration less than the cut-off will generate a line in the test line region. To serve as a procedural control, a colored line will always appear at the control line region indicating that that proper volume of specimen has been added and membrane wicking has occurred.

REAGENTS

The test device contains mouse monoclonal anti-Cotinine antibody-coupled particles and Cotinine-protein conjugate. A goat antibody is employed in the control line system.

PRECAUTIONS

- Do not use after the expiration date.
- The test device should remain in the sealed pouch until use.
- All specimens should be considered potentially hazardous and handled in the same manner as an infectious agent.
- The used test device should be discarded according to local regulations.

STORAGE AND STABILITY

Store as packaged in the sealed pouch either at room temperature or refrigerated (2-30°C). The test device is stable through the expiration date printed on the sealed pouch. The test device must remain in the sealed pouch until use. **DO NOT FREEZE.** Do not use beyond the expiration date.

SPECIMEN COLLECTION AND PREPARATION

Urine Assay

The urine specimen must be collected in a clean and dry container. Urine collected at any time of the day may be used. Urine specimens exhibiting visible precipitates should be centrifuged, filtered, or allowed settle to obtain a clear supernatant for testing.

Specimen Storage

Urine specimens may be stored at 2-8°C for up to 48 hours prior to assay. For prolonged storage, specimens may be frozen and stored below -20°C. Frozen specimens should be thawed and mixed before testing.

MATERIALS

Materials Provided

- Test devices
- Droppers
- Package insert

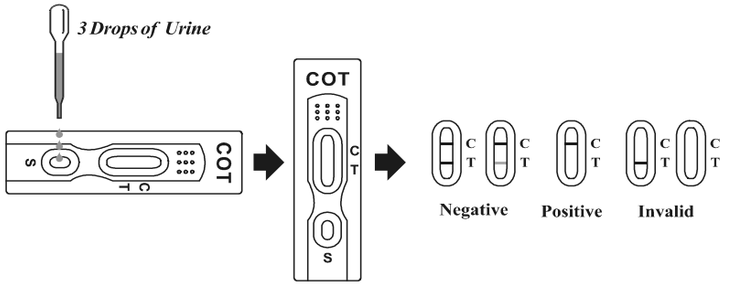
Materials Required But Not Provided

- Specimen collection container
- Timer

DIRECTIONS FOR USE

Allow test device, urine specimen to reach room temperature (15-30°C) prior to testing.

1. Bring the pouch to room temperature before opening it. Remove the test device from the sealed pouch and use it as soon as possible.
2. Place the test device on a clean and level surface. Hold the dropper vertically and **transfer 3 full drops of urine** (approx. 100 µL) to the specimen well (S) of the test device, and then start the timer. Avoid trapping air bubbles in the specimen well (S). See the illustration below.
3. Wait for the colored line(s) to appear. The result should be **read at 5 minutes**. It is important that the background is clear before the result is read. Do not interpret the result after 10 minutes.



INTERPRETATION OF RESULTS

(Please refer to the illustration above)

NEGATIVE:* Two lines appear. One colored line should be in the control line region (C), and another apparent colored line should be in the test line region (T). This negative result indicates that the Cotinine concentration is below the detectable level (200 ng/mL).

***NOTE:** The shade of color in the test line region (T) may vary, but it should be considered negative whenever there is even a faint line.

POSITIVE: One colored line appears in the control line region (C). No line appears in the test line region (T). This positive result indicates that the Cotinine concentration exceeds the detectable level (200 ng/mL).

INVALID: Control line fails to appear. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test using a new test device. If the problem persists, discontinue using the lot immediately and contact your local distributor.

QUALITY CONTROL

A procedural control is included in the test. A colored line appearing in the control line region (C) is considered an internal procedural control. It confirms sufficient specimen volume, adequate membrane wicking and correct procedural technique.

LIMITATION

1. The COT One Step Cotinine Test Device (Urine) provides only a qualitative, preliminary analytical result. A secondary analytical method must be used to obtain a confirmed result. Gas chromatography/mass spectrometry (GC/MS) is the preferred confirmatory method.[1,2]
2. It is possible that technical or procedural errors, as well as other interfering substances in the urine specimen may cause erroneous results.
3. Adulterants, such as bleach and/or alum, in urine specimens may produce erroneous results regardless of the analytical method used. If adulteration is suspected, the test should be repeated with another urine specimen.
4. A positive result indicates only that the presence of Cotinine is above the cut-off concentration. It does not indicate or measure level of consumption.

PERFORMANCE CHARACTERISTICS

Accuracy

A side-by-side comparison was conducted using the COT One Step Cotinine Test Device (Urine) and a leading commercially available COT rapid test. Testing was performed on 300 clinical specimens collected from smoking and non-smoking volunteers. The following results were tabulated:

Method		Other COT Rapid Test		Total
COT One Step Test Device	Results	Positive	Negative	Results
	Positive	103	12	115
	Negative	0	185	185
Total Results		103	197	300
% Agreement		>99%	94%	96%

Analytical Sensitivity

A drug-free urine pool was spiked with Cotinine at the following concentrations: 0 ng/mL, 100 ng/mL, 150 ng/mL, 200 ng/mL, 250 ng/mL, 300 ng/mL and 400 ng/mL. The result demonstrates > 99% accuracy at 100% above and 50% below the cut-off concentration. The data are summarized below:

Cotinine Concentration (ng/mL)	Percent of Cut-off	n	Visual Result	
			Negative	Positive
0	0	90	90	0
100	-50%	90	90	0
150	-25%	90	90	0
200	Cut-off	90	63	27
250	+25%	90	40	50
300	+50%	90	16	74
400	+100%	90	0	90

Analytical Specificity

The following table lists compounds that are positively detected in urine by the COT One Step Cotinine Test Device (Urine) at 5 minutes.

Compound	Concentration (ng/mL)
(-)-Cotinine	200
(-)-Nicotine	6,250

Precision

A study was conducted by trained operators using 2 different lots of product to demonstrate the within run, between run and between operator precision. An identical panel of coded specimens containing no Cotinine, 50% Cotinine below cut-off level and 100% Cotinine above the 200 ng/mL cutoff level were used. The following results were tabulated:

Cotinine Concentration (ng/mL)	n per lot	Lot A		Lot B	
		-	+	-	+
0	30	30	0	30	0
100	30	30	0	30	0
400	30	0	30	0	30

Effect of Urinary Specific Gravity

Fifteen urine specimens of normal, high, and low specific gravity ranges were spiked with 100 ng/mL and 400 ng/mL of Cotinine. The COT One Step Cotinine Test Device (Urine) was tested in duplicate using the fifteen neat and spiked urine specimens. The results demonstrate that varying ranges of urinary specific gravity do not affect the test results.

Effect of Urinary pH

The pH of an aliquoted negative urine pool was adjusted to a pH range of 5 to 9 in 1 pH unit increments and spiked with Cotinine to 100 ng/mL and 400 ng/mL. The spiked, pH-adjusted urine was tested with the COT One Step Cotinine Test Device (Urine) in duplicate. The results demonstrate that varying ranges of pH do not interfere with the performance of the test.

Cross-Reactivity

A study was conducted to determine the cross-reactivity of the test with compounds in either drug-free urine or Cotinine positive urine. The following compounds show no cross-reactivity when tested with the COT One Step Cotinine Test Device (Urine) at a concentration of 100 µg/mL.

Non Cross-Reacting Compounds

4-Acetaminophenol	Acetone	Acetophenetidin	Acetylsalicyclic acid
Albumin	Aminopyrine	Amitryptyline	Amobarbital
Amoxapine	Amoxicillin	l-Amphetamine	Ampicillin
Apomorphine	Aspartame	Atropine	Benzilic acid
Benzoic acid	Benzoylecgonine	Benzphetaminne	Bilirubin
Brompheniramine	Buspirone	Caffeine	Cannabidiol
Cannabinol	Chloral Hydrate	Chloramphenicol	Chlordiazepoxide
Chloroquine	(+)-Chlorpheniramine	(±)Chlorpheniramine	Chlorpromazine
Chlorprothixene	Cholestrol	Cimetidine	Clomipramine
Clonidine	Cocaine	Codeine	Cortisone
Creatinine	Cyclobarbital	Cyclobenzaprine	Deoxycorticosterone
(-) Deoxyephedrine	R(-) Deprenyl	Dextromethorphan	Diazepam
Diclofenac	Digoxin	4-Dimethylaminoantipyrine	Diphenhydramine
5,5-Diphenylhydantoin	Disopyramide	Doxylamine	Ecgonine
Ecgonine Methylester	EDDP	Efavirenz (Sustiva)	EMDP
Ephedrine	(1r,2s)-(-) Ephedrine	(-)ψ-Ephedrine	(±)Epinephrine
Erythromycin	B-Estradiol	Estrone 3-sulfate	Ethanol
Ethyl-p-aminobenzoate	Etodolac	Famprofazone	Fenfluramine
Fenoprofen	Fentanyl	Fluoxetine	Furosemide
Gentisic acid	d (+) Glucose	Guaiacol Glyceryl Ether	Hemoglobin
Hydralazine	Hydrochlorothiazide	Hydrocodone	Hydrocortisone
Hydromorphone	p-Hydroxyamphetamine	o-Hydroxyhippuric acid	p-Hydroxymethamphetamine
p-Hydroxynorephedrine	Hydroxyzine	3-Hydroxytyramine	Ibuprofen
Imipramine	Iproniazid	(-)Isoproterenol	Isoxsuprine
Kanamycin	Ketamine	Ketoprofen	Labetalol
l-Ascorbic acid	l-Ephedrine	l-Epinephrine	Levorphanol
Lidocaine	Lindane	Lithum Carbonate	Loperamide
Maprotiline	Meperidine	Mephentermine	Meprobamate
Methadone	d-Methamphetamine	l-Methamphetamine	Methaqualone
Methoxyphenamine	MDA*	MDMA**	Methylphenidate
Methyprylon	Metoprolol	Morphine Sulfate	Morphine 3-β-d-glucuronide
Nalidixic acid	Nalorphine	Naloxone	Naltrexone
Nimesulide	Norcodeine	a-Naphthaleneactetic acid	Norethindrone
Normorphine	d-Norpropoxyphene	Noscapine	d,l-Octopamine
Orphenadrine	Oxalic acid	Oxazepam	Oxolinic acid
Oxycodone	Oxymetazoline	Oxymorphone	Papaverine
Pemoline	Penicillin-G	Pentazocine	Pentobarbital
Perphenazine	Phencyclidine	Phenelzine	Pheniramine
Phenobarbital	Phenothiazine	Phentermine	Trans-2-phenylcyclopropylamine
l-Phenylephrine	B-Phenylethylamine	d,l Norephedrine	(±)Phenylpropanolamine
Prednisolone	Prednisone	Procaine	Promazine
Promethazine	d,l-Propanolol	d-Propoxyphene	d-Pseudoephedrine
Quinacrine	Quinidine	Quinine	Ranitidine
Riboflavin	Salicylic acid	Secobarbital	Serotonin
Sodium Chloride	Sulfamethazine	Sulindac	Temazepam
Tetracycline	Tetrahydrocortisone	3-acetate Tetrahydrozoline	Thebaine
Theophylline	Thiamine	Thioridazine	l-Thyroxine
Tolbutamine	Cis-Tramadol	Trazodone	Trimterene
Trifluoperazine	Trimethobenzamide	Trimethoprim	Trimipramine
Tryptamine	d,l-Tryptophan	Tyramine	d,l-Tyrosine
Uric Acid	Verapmil	Zomepirac	

*MDA= 3,4-Methylenedioxyamphetamine **MDMA = 3,4-Methylenedioxymethamphetamine

BIBLIOGRAPHY

1. Baselt RC. Disposition of Toxic Drugs and Chemicals in Man. 6th Edition. Biomedical Publications, Foster City, CA. 2002; 744-747
2. Hardman JG and Limbird LE. Goodman and Gilman's: The Pharmacological Basis for Therapeutics. 10th Edition. McGraw Hill Medical Publishing, 2001; 208-209.

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Eff. Date: 2005-04-30

REDWOOD TOXICOLOGY LABORATORY™

State of West Virginia
Purchasing Division

RFQ No. DJS1700000009 - Drug Testing Kits and Supplies
Due Date: April 11, 2017, 1:30 p.m.

TECHNICAL PROPOSAL

Submitted by:

Heather Brautman
Bid Analyst
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3650 Westwind Blvd.
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Phone (800) 255-2159 ext. 34449
Fax (707) 577-8102
hbrautman@redwoodtoxicology.com

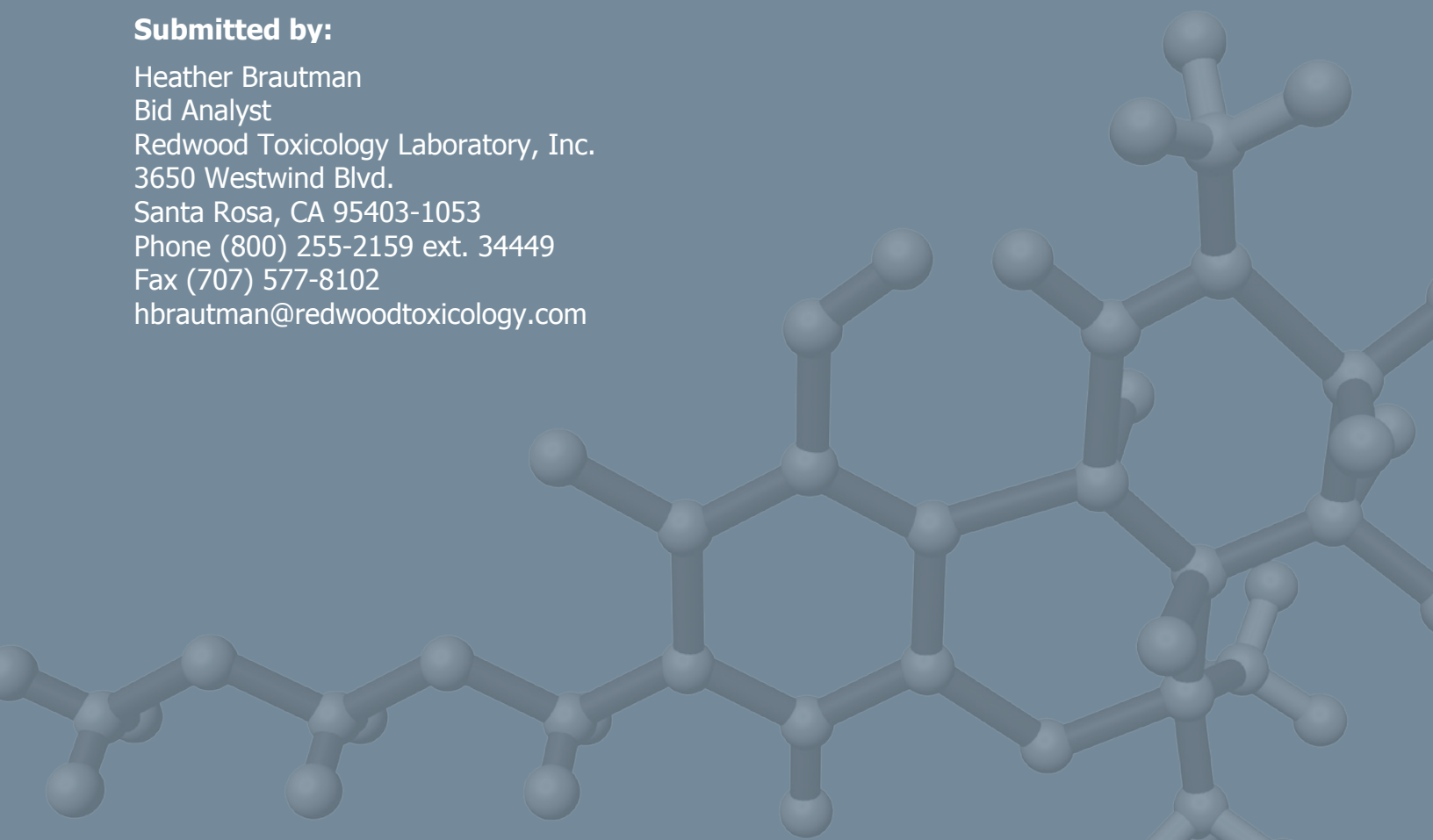

Table of Contents – Cost Proposal

Pricing Page- Exhibit A (Revised)

CRFQ DJS1700000009 Drug Testing Kits and Supplies				
Item #	**Description**	**Estimated Annual Qty.**	**Unit Price**	*** Extended Price**
4.1.1	13 Panel Urine Test Kit	8000	$5.05**^	$40,400.00
4.1.2	Oral Swab Test Kit-6 Panel (Standard) WV DJS USE	500	$5.60^^	$2,800.00
4.1.2.13	Oral Swab Test Kit-6 Panel (Customizable) WV DOC USE	500	$5.60^^	$2,800.00
4.1.3	8 Panel Urine Test Kit (Standard) for WV DJS USE	600	$2.80	$1,680.00
4.1.3.15	8 Panel Urine Test Kit (Customizable) for WV DOC USE	600	$3.72**^^^	$2,232.00
4.1.3.2	Nicotine Test Only	1200	$1.09^^^^	$1,308.00
4.1.3.3	Buprenorphine Test Only	800	$0.45	$360.00
4.1.7	Laboratory Confirmation Services 8 Panel Urine (Price Per Drug)	2000	$11.00	$22,000.00
4.1.7	Laboratory Confirmation Services 13 Panel Urine (Price Per Drug)	2000	$11.00	$22,000.00
4.1.7.7	EtG and EtS testing (All Inclusive)	2000	$10.95	$21,900.00
4.1.7.11	MRO or Lab Rep as Expert Witness (Price Per Hour)	5	$100.00	$500.00
	Failure to use this form may result in disqualification		**Total**	$117,980.00
	Bidder / Vendor Information:			
	Name: Redwood Toxicology Laboratory, Inc.			
	Address: 3650 Westwind Blvd			
	Santa Rosa, CA 95403			
	Phone# : (800) 255-2159			
	Email Address: bids@redwoodtoxicology.com			
	* Multiply bid price by the estimated annual quantity			

**Customizations include standard drugs and adulterants only. For non-standard drugs, the following fees would apply: add $0.46 for Alcohol, add $0.98 for Fentanyl, add $0.52 for Tramadol, add $1.17 for K2/Spice, add $1.43 for EtG, add $0.52 for Cotinine.

^Price is for 13-drug DrugCheck cup with standard drugs and 3 adulterants. If the State is willing to accept slight deviations, RTL will offer the following more cost-effective options: 13-drug iCup (part number 011022028 / no adulterants) or 12-drug iCup (part number 011022027 with adulterants) - $3.10 each. ***This would result in an annual savings of $15,600.00.***

^^Price is for SalivaScreen OFD with standard drugs. If the State is willing to accept slight deviations, RTL will offer the following more cost-effective options: 6-drug iScreen OFD (part number 011022025 / PCP instead of BAR) or Oralert (part number 011022083 / BZO instead of BAR) -$3.85 each. ***This would result in an annual savings of $1,750.00.*** For FDA-cleared Oratect (part number 015770105 / PCP instead of BAR) - $10.24 each.

^^^Price is for 8-drug DrugCheck cup with standard drugs and 3 adulterants. If the DOC is willing to accept the same 8-drug iCup AD (part number 011022038) as was offered for the DJS (non-customizable), RTL will offer the same price: $2.80 each. ***This would result in an annual savings of $552.00.***

^^^^Price is for DrugCheck Cotinine dip. If the State is willing to accept a Cotinine cassette instead of a dip device, RTL will offer the following more cost-effective option: Nicotine cassette (part number 011021950) - $0.65 each. ***This would result in an annual savings of $528.00.***

3650 Westwind Boulevard
Santa Rosa, CA 95492
phone 800.255.2159
fax 707.577.8102

Offered Devices Comparison
State of West Virginia
CRFQ DJS1700000009 Drug Testing Kits and Supplies

To make it easier for the State to see the differences between the device options we have offered, we have created the below Offered Devices Comparison. Please see the included product inserts for each device for more detailed information about the available drugs, correct procedural instructions, and accuracy information.

Item #	Product Type	Part Number	How Differs from Requested Configuration	Customizable?	Includes AD?	FDA-Cleared or FUO	TAT for Results	Results Stability Window	Price
4.1.1	13-Drug DrugCheck Drug Screen Cup	Various	Matches	Yes	Yes	FDA-cleared or FUO, depending on configuration	5 min	10 min	$5.05
	13-Drug iCup	011022028	No AD	No	No	FDA-cleared	5 min	60 min	$3.10
	12-Drug iCup A.D.	011022027	Missing one drug	No	Yes	FDA-cleared	5 min	60 min	$3.10
	12-Drug E-Z Split Key Cup II	011022096	No AD, missing one drug	No	No	FDA-cleared	5 min	60 min	$3.10
4.1.2 & 4.1.2.13	6-Drug Saliva Scan	TBD	Matches	Yes	N/A	FUO	10 min	20 min	$5.60
	6-Drug iScreen OFD	011022025	Has PCP instead of BAR	No	N/A	FUO	10 min	60 min	$3.85
	6-Drug OrAlert	011022083	Has BZO instead of BAR	No	N/A	FUO	9 min	9 min	$3.85
	6-Drug Oratect	015770105	Has PCP instead of BAR	No	N/A	FDA-cleared	5 min	15 min	$10.24
4.1.3.15	8-Drug DrugCheck Drug Screen Cup	Various	Matches	Yes	Yes	FDA-cleared or FUO, depending on configuration	5 min	10 min	$3.72
	8-Drug iCup A.D.	011022038	Matches	No	Yes	FDA-cleared	5 min	60 min	$2.80
4.1.3.2	DrugCheck Cotinine Dip	TBD	Matches	N/A	N/A	FUO	5 min	10 min	$1.09
	RediTest Cotinine Cassette	011021950	Is cassette - uses pipette	N/A	N/A	FUO	5 min	10 min	$0.65

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Additional Optional Pricing Schedule / Catalogue
State of West Virginia
CRFQ DJS1700000009 Drug Testing Kits and Supplies

Section I: Laboratory Drug & Alcohol Testing Services - Urine

Items highlighted in green match line items from the Pricing Page - Exhibit A.

Urine Lab Tests - Standard Drugs

Standard drugs include: Alcohol (Ethanol), Amphetamines/Methamphetamines, Barbiturates, Benzodiazepines, Cocaine, Ecstasy (MDMA), Marijuana (THC), Methadone, Opiates, PCP, Propoxyphene.

TEST CODE	DRUG(S)	DESCRIPTION	PRICE PER SPECIMEN
Various	1	One Drug Standard Urine Lab Panel - Screen Only	$ 3.00
Various	4	Four Drug Standard Urine Lab Panel - Screen Only	$ 3.90
Various	5	Five Drug Standard Urine Lab Panel - Screen Only	$ 4.20
Various	6	Six Drug Standard Urine Lab Panel - Screen Only	$ 4.60
Various	7	Seven Drug Standard Urine Lab Panel - Screen Only	$ 5.00
Various	8	Eight Drug Standard Urine Lab Panel - Screen Only	$ 5.25
Various	9	Nine Drug Standard Urine Lab Panel - Screen Only	$ 5.50
Various	10	Ten Drug Standard Urine Lab Panel - Screen Only	$ 5.75
H58/H59	11	Eleven Drug Standard Urine Lab Panel with Oxycodone - Screen Only	$ 6.00
Various	1	GC-MS, LC-MS/MS or GC-FID Standard Urine Confirmation - cost per drug	$ 11.00
P69	1	Specimen Validity Panel - Creatinine, pH & Specific Gravity	$ 1.25

Urine Lab Tests - Specialty Drugs

TEST CODE	DRUG(S)	DESCRIPTION	PRICE PER SPECIMEN
5210	1	Ambien (Zolpidem)	$ 25.00
092	1	Buprenorphine - Screen Only	$ 5.00
5292	1	Buprenorphine - Confirmation Only	$ 12.50
2267	1	Carisoprodol (Soma) - Screen Only	$ 8.00
5271	1	Carisoprodol (Soma) - Confirmation Only	$ 15.00
1273	1	Cotinine (Nicotine metabolite) - Screen Only	$ 5.00
1243	1	Dextromethorphan - Screen Only	$ 8.00
5243	1	Dextromethorphan - Confirmation Only	$ 15.00
N/A	1	Ethyl Glucuorinde (EtG) Alcohol Metabolite - Add-On Screen Only **Price added on when built into standard panel*	$ 2.00
049 or 050	1	Ethyl Glucuronide (EtG) Alcohol Metabolite - Stand-Alone Screen Only	$ 5.00
646 or 647	1	Ethyl Glucuronide/Ethyl Sulfate (EtG/EtS) Alcohol metabolite - EtG Screen with Automatic Confirmation of Positives for both EtG & EtS	$ 10.95
5504	1	Fentanyl	$ 40.00
5503	1	GHB	$ 50.00
094	1	Heroin metabolite (6-MAM) - Screen Only	$ 3.50
5094	1	Heroin metabolite (6-MAM) - Confirmation Only	$ 12.50
5501	1	Ketamine	$ 15.00
5960	1	Kratom	$ 80.00
1163	1	LSD	$ 15.00
N/A	1	Oxycodone - Add-On Screen Only	$ 1.00
098	1	Oxycodone - Stand-Alone Screen Only	$ 5.00
5098	1	Oxycodone - Confirmation Only	$ 12.50
091	1	Tramadol - Screen Only	$ 8.00
5212	1	Tramadol - Confirmation Only	$ 15.00

Urine Lab Tests - Specialty Drug Panels

TEST CODE	DRUG(S)	DESCRIPTION	PRICE PER SPECIMEN
P45	Multi	Comprehensive Panel - Screen Only / Confirmation for additional fee of $20.00 per drug. Detects over 600 brand name prescription drugs, ilicit drugs, and alcohol.	$ 50.00
P80	21	Designer Stimulants (Bath Salts) - Expanded Panel	$ 30.00
P81	3	Designer Stimulants (Bath Salts) - Short Panel (MDPV, Mephedrone, Methylone)	$ 18.00
6473	19	Synthetic Marijuana (K2/Spice) - Standard Panel	$ 18.00
8474	30	Synthetic Marijuana (K2/Spice) - Premium Panel	$ 45.00
5550	Multi	Steroid Testing	$ 65.00

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Additional Optional Pricing Schedule / Catalogue
State of West Virginia
CRFQ DJS1700000009 Drug Testing Kits and Supplies

Section II: Laboratory Drug & Alcohol Testing Services - Oral Fluids

Items highlighted in green match line items from the Pricing Page - Exhibit A.

Oral Fluid Lab Tests - Standard Drugs

Standard drugs include: Alcohol (Ethanol), Amphetamines, Barbiturates, Benzodiazepines, Cocaine, Marijuana (THC), Methadone, Methamphetamines, Opiates, Oxycodone, PCP.

TEST CODE	DRUG(S)	DESCRIPTION	PRICE PER SPECIMEN
2101001	N/A	Quantisal Oral Fluid Collection Device - *purchase required prior to testing*	$ 2.00
Various	1	GC-MS, LC-MS/MS or GC-FID Standard Oral Fluid Confirmation - cost per drug	$ 11.00
Various	6	Six Drug Standard Oral Fluid Lab Panel - Screen Only	$ 6.00
Various	7	Seven Drug Standard Oral Fluid Lab Panel - Screen Only	$ 7.00
Various	8	Eight Drug Standard Oral Fluid Lab Panel - Screen Only	$ 8.00
Various	9	Nine Drug Standard Oral Fluid Lab Panel - Screen Only	$ 9.00
Various	10	Ten Drug Standard Oral Fluid Lab Panel - Screen Only	$ 10.00
Various	11	Eleven Drug Standard Oral Fluid Lab Panel - Screen Only	$ 11.00
Various	6	Six Drug Standard Oral Fluid Lab Panel - Screen + Auto Confirm of Positives	$ 12.00
Various	7	Seven Drug Standard Oral Fluid Lab Panel - Screen + Auto Confirm of Positives	$ 13.00
Various	8	Eight Drug Standard Oral Fluid Lab Panel - Screen + Auto Confirm of Positives	$ 14.00
Various	9	Nine Drug Standard Oral Fluid Lab Panel - Screen + Auto Confirm of Positives	$ 15.00
Various	10	Ten Drug Standard Oral Fluid Lab Panel - Screen + Auto Confirm of Positives	$ 16.00
Various	11	Eleven Drug Standard Oral Fluid Lab Panel - Screen + Auto Confirm of Positives	$ 17.00

Oral Fluid Lab Tests - Specialty Drugs

TEST CODE	DRUG(S)	DESCRIPTION	PRICE PER SPECIMEN
N/A	1	Buprenorphine - Add to a screen only panel	$ 1.00
N/A	1	Buprenorphine - Add to an automatic confirmation panel	$ 1.50
F25	19	Synthetic Cannabinoids (K2/Spice)	$ 18.00
TBD	N/A	Designer Stimulants (Bath Salts)	$ 25.00
TBD	N/A	Tramadol	$ 25.00

Section III: Laboratory Supplemental Services

Problematic Specimen Charges and Additional Service Charges

TEST CODE	DESCRIPTION	PRICE PER OCCURRENCE
QNS	Insufficient Volume	$ -
PROB	Chain of Custody (COC) and/or Specimen Label Errors	$ -
	Product and/or Supply Shipping Errors due to Incorrect Address Provided	$ -
ADS	Accidental Delivery Specimen - Specimen Sent to RTL in Error	$ -
PULL	Specimen Retrieval from Storage for Follow-Up Testing	$ -
FEDEX	Short Shipment - Less than Five (5) Specimens	$ -
AFFD	Affidavits	$ -
INTP	Interpretations	$ -
STAT	STAT Testing Requests (Priority)	$ 100.00
CORT	Telephonic or Webinar Court Testimony	$ -
	In-Person Court Testimony	$100/hour

Collection & Shipping Supplies

RTL provides all necessary urine specimen collection and shipping supplies to its clients at no additional cost. For urine testing, these supplies include:

- Urine specimen collection containers: 60 mL or 90mL bottles with lids and built-in temperature strips.
- Specimen baggies with absorbent material
- Preprinted Chain of Custody forms/labels & security seals
- Pre-paid FedEx or UPS lab packs or pre-paid U.S. mailer boxes.

Lab Supply Shipping and Handling: Outbound lab supply orders will be shipped at no charge for ground service delivery. Expedited shipping of supplies will be charged on an 'at cost' basis. FOB Destination per bid specifications.

Specimen Shipment to RTL: Next day air service of inbound specimens sent to RTL for testing is provided at no charge; however, it is requested that five (5) or more urine and/or oral fluids specimens are sent in each FedEx overnight shipment. Any combination of urine and/or oral fluids devices may be shipped together via FedEx overnight service.

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Additional Optional Pricing Schedule / Catalogue
State of West Virginia
CRFQ DJS1700000009 Drug Testing Kits and Supplies

Section IV: Rapid Drug & Alcohol Screening Devices - Urine

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PANEL-DIP SUBSTANCE ABUSE TEST DEVICE

PART NUMBER	DRUG(S)	CONFIGURATION	PRICE PER DEVICE	BOX PRICE (25/BOX)
01 102 0018	1	PANEL DIP 01 AMPHETAMINES 1000 (AMP 1000)	$0.33	$8.25
01 102 0019	1	PANEL DIP 01 BARBITURATES 300 (BAR)	$0.33	$8.25
01 102 0022	1	PANEL DIP 01 BENZODIAZEPINES 300 (BZO)	$0.33	$8.25
01 102 0189	1	PANEL DIP 01 COCAINE 150 (COC 150)	$0.33	$8.25
01 102 0001	1	PANEL DIP 01 COCAINE 300 (COC 300)	$0.33	$8.25
01 102 0036	1	PANEL DIP 01 ECSTASY 500 (MDMA)	$0.33	$8.25
01 102 0004	1	PANEL DIP 01 MARIJUANA 50 (THC)	$0.33	$8.25
01 102 0020	1	PANEL DIP 01 METHADONE 300 (MTD)	$0.33	$8.25
01 102 0190	1	PANEL DIP 01 METHAMPHETAMINES 500 (MAMP 500)	$0.33	$8.25
01 102 0002	1	PANEL DIP 01 METHAMPHETAMINES 1000 (MAMP 1000)	$0.33	$8.25
01 102 0003	1	PANEL DIP 01 OPIATES 300 (MOP 300)	$0.33	$8.25
01 102 1977	1	PANEL DIP 01 OPIATES 2000 (OPI 2000)	$0.33	$8.25
01 102 0037	1	PANEL DIP 01 OXYCODONE 100 (OXY)	$0.33	$8.25
01 102 0021	1	PANEL DIP 01 PHENCYCLIDINE 20 (PCP)	$0.33	$8.25
01 102 1971	1	PANEL DIP 01 PROPOXYPHENE 300 (PPX)	$0.33	$8.25
01 102 0023	1	PANEL DIP 01 TRICYCLIC ANTIDEPRESSANTS 1000 (TCA)	$0.33	$8.25
01 102 0173	1	PANEL DIP 01 BUPRENORPHINE 10 (BUP)	$0.45	$11.25
01 501 0008	1	PANEL DIP 01 EtG 500 - ***For Forensic Use Only***	$3.00	$75.00
01 501 0009	1	PANEL DIP 01 FENTANYL 200 - ***For Forensic Use Only***	$2.50	$62.50
01 191 6335	1	PANEL DIP 01 K2 SPICE 30 - ***For Forensic Use Only***	$2.00	$50.00
01 102 0005	2	PANEL DIP 02 COC300/MOP300	$0.67	$16.75
01 102 0006	2	PANEL DIP 02 COC300/THC	$0.67	$16.75
01 102 0007	2	PANEL DIP 02 COC300/MAMP1000	$0.67	$16.75
01 102 0008	2	PANEL DIP 02 MAMP1000/THC	$0.67	$16.75
01 102 0030	2	PANEL DIP 02 MAMP1000/MOP300	$0.67	$16.75
01 102 0191	2	PANEL DIP 02 COC150/THC	$0.67	$16.75
01 102 0192	2	PANEL DIP 02 MAMP500/THC	$0.67	$16.75
01 102 0009	3	PANEL DIP 03 COC300/MAMP1000/THC	$0.86	$21.50
01 102 0010	3	PANEL DIP 03 COC300/MOP300/THC	$0.86	$21.50
01 102 0011	3	PANEL DIP 03 MAMP1000/MOP300/THC	$0.86	$21.50
01 102 0014	3	PANEL DIP 03 COC300/MAMP1000/MOP300	$0.86	$21.50
01 102 0193	3	PANEL DIP 03 COC150/MAMP500/THC	$0.86	$21.50
01 102 0194	3	PANEL DIP 03 COC150/MOP300/THC	$0.86	$21.50
01 102 0012	4	PANEL DIP 04 COC300/MAMP1000/MOP300/THC	$1.13	$28.25
01 102 0032	4	PANEL DIP 04 AMP1000/COC300/MOP300/THC	$1.13	$28.25
01 102 0195	4	PANEL DIP 04 COC150/MAMP500/MOP300/THC	$1.13	$28.25
01 102 0199	4	PANEL DIP 04 AMP1000/COC150/MOP300/THC	$1.13	$28.25
01 102 0013	5	PANEL DIP 05 COC300/MAMP1000/MOP300/PCP/THC	$1.39	$34.75
01 102 0015	5	PANEL DIP 05 BZO/COC300/MAMP1000/MOP300/THC	$1.39	$34.75
01 102 0033	5	PANEL DIP 05 AMP1000/COC300/MOP300/PCP/THC	$1.39	$34.75
01 102 0034	5	PANEL DIP 05 AMP1000/COC300/MAMP1000/MOP300/THC	$1.39	$34.75
01 102 0047	5	PANEL DIP 05 AMP1000/COC300/OPI2000/PCP/THC	$1.39	$34.75
01 102 0201	5	PANEL DIP 05 AMP1000/COC150/MAMP500/MOP300/THC	$1.39	$34.75
01 102 0196	5	PANEL DIP 05 COC150/MAMP500/MOP300/PCP/THC	$1.39	$34.75
01 102 0200	5	PANEL DIP 05 AMP1000/COC150/MOP300/PCP/THC	$1.39	$34.75

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Additional Optional Pricing Schedule / Catalogue
State of West Virginia
CRFQ DJS1700000009 Drug Testing Kits and Supplies

Section IV: Rapid Drug & Alcohol Screening Devices - Urine

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PANEL-DIP SUBSTANCE ABUSE TEST DEVICE (CONTINUED)

PART NUMBER	DRUG(S)	CONFIGURATION	PRICE PER DEVICE	BOX PRICE (25/BOX)
01 102 0016	6	PANEL DIP 06 BZO/COC300/MAMP1000/MOP300/PCP/THC	$1.62	$40.50
01 102 0017	6	PANEL DIP 06 BZO/COC300/MAMP1000/MTD/MOP300/THC	$1.62	$40.50
01 102 0024	6	PANEL DIP 06 BAR/BZO/COC300/MAMP1000/MOP300/THC	$1.62	$40.50
01 102 0119	6	PANEL DIP 06 BZO/COC300/MAMP1000/MOP300/OXY/THC	$1.62	$40.50
01 102 0175	6	PANEL DIP 06 BZO/COC150/MAMP500/MDMA/MOP300/THC	$1.62	$40.50
01 102 0202	6	PANEL DIP 06 BZO/COC150/MAMP500/MOP300/OXY/THC	$1.62	$40.50
01 102 0203	6	PANEL DIP 06 AMP1000/BZO/COC150/MAMP500/MOP300/THC	$1.62	$40.50
01 102 0035	7	PANEL DIP 07 AMP1000/BZO/COC150/MOP300/PCP/TCA/THC	$1.89	$47.25
01 102 0176	7	PANEL DIP 07 BZO/COC150/MAMP500/MDMA/MOP300/OXY/THC	$1.89	$47.25
01 102 0177	7	PANEL DIP 07 AMP1000/COC150/MAMP500/MDMA/MOP300/OXY/THC	$1.89	$47.25
01 102 0169	8	PANEL DIP 08 AMP1000/BZO/COC300/MAMP1000/MDMA/MOP300/OXY/THC	$2.14	$53.50
01 102 0179	8	PANEL DIP 08 AMP1000/BZO/COC300/MAMP1000/MOP300/OXY/PCP/THC	$2.14	$53.50
01 102 1989	8	PANEL DIP 08 AMP300/COC150/MAMP500/MOP300/PCP/PPX/OXY/THC	$2.14	$53.50
01 102 1970	9	PANEL DIP 09 AMP1000/BAR/BZO/COC300/MAMP1000/MTD/OPI2000/PCP/THC	$2.40	$60.00
01 102 0180	9	PANEL DIP 09 AMP1000/BUP/BZO/COC300/MAMP1000/MOP300/OXY/PCP/THC	$2.40	$60.00
01 102 0181	9	PANEL DIP 09 AMP300/BZO/COC150/MAMP500/MDMA/MOP300/OXY/PCP/THC	$2.40	$60.00
01 102 0025	10	PANEL DIP 10 AMP1000/BAR/BZO/COC300/MAMP1000/MTD/MOP300/PCP/TCA/ THC	$2.66	$66.50
01 102 0138	10	PANEL DIP 10 COC300/BAR/BZO/MAMP1000/MDMA/MOP300/MTD/OXY/PCP/THC	$2.66	$66.50
01 102 0182	10	PANEL DIP 10 AMP1000/BAR/BUP/BZO/COC300/MAMP1000/MOP300/MTD/OXY/ THC	$2.66	$66.50
01 102 0183	10	PANEL DIP 10 BAR/BZO/COC150/MAMP500/MDMA/MOP300/MTD/OXY/PCP/THC	$2.66	$66.50
01 102 1943	10	PANEL DIP 10 AMP1000/BAR/BZO/COC300/MAMP1000/OPI2000/PCP/MTD/MDMA/ THC	$2.66	$66.50
01 102 0184	11	PANEL DIP 11 AMP1000/BAR/BUP/BZO/COC300/MAMP1000/MOP300/MTD/PCP/ OXY/THC	$3.19	$79.75
01 102 0185	11	PANEL DIP 11 AMP1000/BAR/BUP/BZO/COC300/OPI2000/MAMP1000/MTD/OXY/ PCP/THC	$3.19	$79.75
01 102 0186	11	PANEL DIP 11 AMP1000/BAR/BUP/BZO/COC300/MAMP1000/MOP300/MTD/PPX/ OXY/THC	$3.19	$79.75
01 102 0187	11	PANEL DIP 11 AMP300/BAR/BZO/COC150/MAMP500/MDMA/MOP300/MTD/OXY/ PCP/THC	$3.19	$79.75
01 102 0141	12	PANEL DIP 12 AMP1000/BAR/BZO/COC300/MAMP1000/MDMA/MOP300/MTD/ OXY/PCP/PPXTHC	$3.72	$93.00
01 102 0188	12	PANEL DIP 12 AMP1000/BAR/BUP/BZO/COC300/MAMP1000/MDMA/MOP300/ MTD/OXY/PCP/THC	$3.72	$93.00
01 102 1957	12	PANEL DIP 12 AMP1000/BAR/BZO/COC300/MAMP1000/MDMA/OPI2000/MTD/ OXY/PCP/PPX/THC	$3.72	$93.00

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Additional Optional Pricing Schedule / Catalogue
State of West Virginia
CRFQ DJS1700000009 Drug Testing Kits and Supplies

Section IV: Rapid Drug & Alcohol Screening Devices - Urine

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iCUP SUBSTANCE ABUSE TEST DEVICE – without adulteration

PART NUMBER	DRUG(S)	CONFIGURATION	PRICE PER DEVICE	BOX PRICE (25/BOX)
01 102 2020	10	iCup 10 AMP1000/BAR/BZO/COC300/MAMP1000/MDMA/OPI2000/OXY/PPX/THC	$3.20	$80.00
01 102 2055	10	iCup 10 AMP1000/BAR/BZO/COC300/MAMP/MTD/OPI2000/PCP/TCA/THC	$3.20	$80.00
01 102 2028	13	iCup 13 AMP1000/BAR/BUP/BZO/COC300/MAMP/MTD/OPI2000/OXY/PCP/PPX/ TCA/THC	$3.10	$77.50

iCUP A.D. SUBSTANCE ABUSE TEST DEVICE – with adulteration

PART NUMBER	DRUG(S)	CONFIGURATION	PRICE PER DEVICE	BOX PRICE (25/BOX)
01 102 2032	4	iCup A.D. 04 COC300/MAMP1000/OPI2000/THC w/adulteration (OX, SG, PH)	$2.25	$56.25
01 102 2033	4	iCup A.D. 04 AMP1000/COC150/MAMP500/THC w/adulteration (OX, CR, PH)	$2.25	$56.25
01 102 2021	5	iCup A.D. 5 AMP1000/COC300/MAMP1000/MOP300/THC w/adulteration (OX, SG, PH)	$2.25	$56.25
01 102 2034	5	iCup A.D. 5 AMP1000/COC300/MAMP1000/OPI2000/THC w/adulteration (OX, SG, PH)	$2.25	$56.25
01 102 2035	5	iCup A.D. 5 AMP1000/COC300/OPI2000/PCP/THC w/adulteration (OX, SG, PH)	$2.25	$56.25
01 102 2036	5	iCup A.D. 5 COC300/MAMP1000/OPI2000/PCP/THC w/adulteration (OX, SG, PH)	$2.25	$56.25
01 102 2022	6	iCup A.D. 6 AMP1000/BZO/COC300/MAMP1000/OPI2000/THC w/adulteration (OX, SG, PH)	$2.48	$62.00
01 102 2023	6	iCup A.D. 6 AMP1000/COC/MAMP1000/OPI2000/PCP/THC w/adulteration (OX, SG, PH)	$2.48	$62.00
01 102 2037	6	iCup A.D. 06 AMP300/COC300/MDMA/OPI2000/OXY/THC w/adulteration (OX, SG, PH)	$2.48	$62.00
01 102 2038	8	iCup A.D. 08 AMP1000/BAR/BZO/COC300/MAMP1000/OPI2000/PCP/THC w/adulteration (OX, SG, PH)	$2.88	$72.00
01 102 2069	8	iCup A.D. 08 AMP1000/BZO/COC300/MAMP1000/MOP300/OXY/PCP/THC w/adulteration (OX,CR,PH)	$2.88	$72.00
01 102 2039	9	iCup A.D. 09 AMP1000/BAR/BZO/COC300/MAMP1000/MTD/OPI2000/PCP/THC w/adulteration (OX, SG, PH)	$3.11	$77.75
01 102 2074	10	iCup A.D. 10 AMP1000/BAR/BZO/COC300/MAMP1000/MTD/OPI2000/OXY/ PPX/THC w/adulteration (OX, CR, PH)	$3.20	$80.00
01 102 2129	10	iCup A.D. 10 AMP1000/BAR/BZO/COC300/MAMP1000/MTD/OPI2000/PCP/TCA/ THC w/adulteration (OS, SG, PH, NI, GL, CR)	$3.20	$80.00
01 102 2027	12	iCup A.D. AMP1000/BAR/BZO/COC300/MAMP1000/MTD/OPI2000/OXY/PCP/PPX/ TCA/THC w/adulteration (OX, SG, PH)	$3.10	$77.50

INTEGRATED CUPS II SUBSTANCE ABUSE TEST DEVICE

PART NUMBER	DRUG(S)	CONFIGURATION	PRICE PER DEVICE	BOX PRICE (25/BOX)
01 102 2001	4	EZ CUP II 04 COC300/MAMP1000/OPI2000/THC	$2.25	$56.25
01 102 1974	5	EZ CUP II 05 AMP1000/COC300/OPI2000/PCP/THC w/adulteration (OX/SG/PH/NI/GL/CR)	$2.25	$56.25
01 102 2005	5	EZ CUP II 05 COC300/MAMP1000/OPI2000/PCP/THC	$2.25	$56.25
01 102 2018	5	EZ CUP II 05 AMP1000/COC300/MAMP1000/OPI2000/THC	$2.25	$56.25
01 102 2048	5	EZ CUP II 05 AMP1000/COC300/OPI2000/PCP/THC	$2.25	$56.25
01 102 2051	5	EZ CUP II 05 AMP1000/COC300/MAMP1000/OPI2000/THC w/adulteration (OX, SG, PH, NI, GL, CR)	$2.25	$56.25
01 102 2141	5	EZ CUP II 05 AMP1000/COC300/MAMP1000/OPI2000/THC w/adulteration (OX, SG, PH)	$2.25	$56.25
01 102 1984	6	EZ CUP II 06 AMP1000/BZO/COC300/MAMP1000/OPI2000/THC	$2.48	$62.00
01 102 2007	6	EZ CUP II 06 COC300/MAMP1000/MDMA/OPI2000/OXY/THC	$2.48	$62.00
01 102 2008	8	EZ CUP II 08 AMP1000/BAR/BZO/COC300/MAMP1000/OPI2000/PCP/THC	$2.88	$72.00
01 102 2140	9	EZ CUP II 09 BAR/BZO/COC300/MAMP1000/MTD/OPI2000/OXY/PPX/THC w/adulteration (OX, SG, PH)	$3.11	$77.75
01 102 1985	10	EZ CUP II 10 AMP1000/BAR/BZO/COC300/MAMP1000/MDMA/MTD/OPI2000/ PCP/THC	$3.20	$80.00
01 102 2096	12	EZ CUP II 12 AMP1000/BAR/BUP/BZO/COC150/MAMP1000/MDMA/MOP300/ MTD/OXY/PPX/THC	$3.10	$77.50

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Additional Optional Pricing Schedule / Catalogue
State of West Virginia
CRFQ DJS1700000009 Drug Testing Kits and Supplies

Section IV: Rapid Drug & Alcohol Screening Devices - Urine

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DRUGCHECK DRUG SCREEN CUPS

PART NUMBER	DRUG(S)	CONFIGURATION	PRICE PER DEVICE	BOX PRICE (25/BOX)
TBD	8	8-Drug Customizable DrugCheck Cup with 3 Adulteration	$3.72	$93.00
TBD	13	13-Drug Customizable DrugCheck Cup with 3 Adulteration	$5.05	$126.25
N/A	Option	Standard Drug options include: AMP1000, BAR300, BUP10, BZO300, COC150, COC300, MDMA500, MET500, MET1000, MTD300, OPI300, OPI2000, OXY100, PCP25, PPX300, TCA 1000, THC50	N/A	N/A
N/A	Option	Specimen Validity Measure (Adulteration) options include: Creatinine, Nitrite, pH, Oxidants, or Specific Gravity	N/A	N/A
N/A	Option	Add Alcohol - ***FFUO Only***	$0.46	N/A
N/A	Option	Replace Standard Drug with Fentanyl - ***FFUO Only***	$0.98	N/A
N/A	Option	Replace Standard Drug with Tramadol - ***FFUO Only***	$0.52	N/A
N/A	Option	Replace Standard Drug with K2/Spice - ***FFUO Only***	$1.17	N/A
N/A	Option	Replace Standard Drug with EtG - ***FFUO Only***	$1.43	N/A
N/A	Option	Replace Standard Drug with Cotinine - ***FFUO Only***	$0.52	N/A

Section V: Rapid Drug & Alcohol Screening Devices - Oral Fluid & Other Devices

ORAL FLUID DRUGS OF ABUSE - ***For Forensic Use Only***

PART NUMBER	DRUG(S)	CONFIGURATION	PRICE PER DEVICE	BOX PRICE (25/BOX)
01 102 2024	5	iScreen Oral Fluid Device AMP50/COC20/MAMP50/OPI40/THC12 - ***FFUO***	$5.60	$140.00
01 102 2025	6	iScreen Oral Fluid Device AMP50/COC20/MAMP50/OPI40/PCP10/THC12 - ***FFUO***	$3.85	$96.25
01 102 1960	6	OrAlert 6 Oral Fluid Device AMP50/COC20/MAMP50/OPI40/PCP10/THC100 - ***FFUO***	$5.00	$125.00
01 102 2083	6	OrAlert 6 Oral Fluid Device AMP50/BZO10/COC20/MAMP50/OPI40/THC100 - ***FFUO***	$3.85	$96.25
01 577 0105	5	Oratect Oral Fluid Device AMP50/COC20/MAMP50/OPI40/PCP10/THC40 - ***FDA Cleared***	$10.24	$256.00

DRUGCHECK SALIVASCAN

PART NUMBER	DRUG(S)	CONFIGURATION	PRICE PER DEVICE	BOX PRICE (25/BOX)
TBD	6	6-Drug Customizable DrugCheck SalivaScan Oral Fluid Device - ***FFUO***	$5.60	$140.00
N/A	Option	Standard Drug options include: AMP50, BZO50, BAR50, BUP5, COC20, THC12, THC50, MTD30, MET50, OPI40, OXY40, PCP10, PPX50	N/A	N/A

SALIVA/BREATH ALCOHOL PRODUCTS

PART NUMBER	DRUG(S)	CONFIGURATION	PRICE PER DEVICE	BOX PRICE (25/BOX)
01 362 0001	N/A	Instant Alcohol Saliva Test Strip - ***FFUO***	$0.80	$20.00
01 094 0055	N/A	Alco-Screen Test (24/box)	$1.35	$32.40
01 094 0056	N/A	Alco-Screen .02 DOT Approved Alcohol Saliva (24/box)	$1.35	$32.40

REDISMOKE, PREGNANCY & ADULTERATION

PART NUMBER	DRUG(S)	CONFIGURATION	PRICE PER DEVICE	BOX PRICE (25/BOX)
01 102 0140	1	Urine Cotinine (Nicotine Metabolite) Cassette Device - ***FFUO***	$0.65	$16.25
01 102 1950	N/A	Urine Pregnancy Cassette (40/Box)	$1.00	$40.00
01 102 1910	7	One Step Validity Test (Seven Parameter) - ***FFUO***	$0.68	$17.00

DRUGCHECK URINE DRUG SCREEN DIP

PART NUMBER	DRUG(S)	CONFIGURATION	PRICE PER DEVICE	BOX PRICE (25/BOX)
TBD	1	Cotinine (Nicotine metabolite) Dip	$1.09	$27.25

COLLECTION SUPPLIES

PART NUMBER	DRUG(S)	CONFIGURATION	PRICE PER DEVICE	BOX PRICE (25/BOX)
031234	N/A	90 ml Urine Collection Bottle with Built-in Temp Strip	$0.00	$0.00
031380	N/A	6.5 oz/ Graduated Beaker	$0.00	$0.00
031258	N/A	Temperature Strip	$0.00	$0.00

Device Order Shipping & Handling: Device orders will be shipped at no charge for ground service delivery. Expedited shipping of device orders will be charged on an 'at cost' basis. FOB Destination per bid specifications.