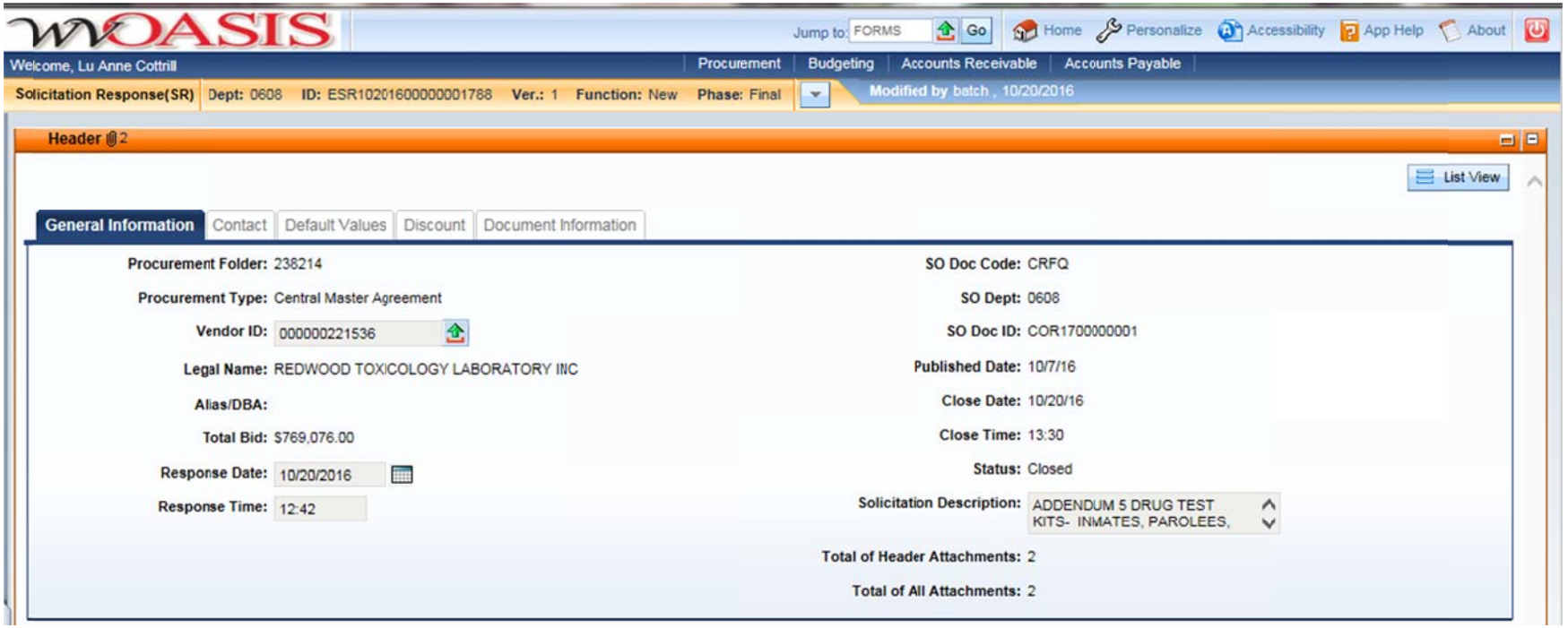
The following documentation is an electronically-submitted vendor response to an advertised solicitation from the *West Virginia Purchasing Bulletin* within the Vendor Self-Service portal at ***wvOASIS.gov***. As part of the State of West Virginia's procurement process, and to maintain the transparency 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
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Welcome, Lu Anne Cottrill
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Solicitation Response(SR) Dept: 0608 ID: ESR10201600000001788 Ver.: 1 Function: New Phase: Final
Modified by batch , 10/20/2016
Header 2
List View
General Information
Contact
Default Values
Discount
Document Information
Procurement Folder: 238214
Procurement Type: Central Master Agreement
Vendor ID: 000000221536
Legal Name: REDWOOD TOXICOLOGY LABORATORY INC
Alias/DBA:
Total Bid: $769,076.00
Response Date: 10/20/2016
Response Time: 12:42
SO Doc Code: CRFQ
SO Dept: 0608
SO Doc ID: COR1700000001
Published Date: 10/7/16
Close Date: 10/20/16
Close Time: 13:30
Status: Closed
Solicitation Description: ADDENDUM 5 DRUG TEST KITS- INMATES, PAROLEES,
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 : 238214

Solicitation Description : ADDENDUM 5 DRUG TEST KITS- INMATES, PAROLEES, AND EMPLOYEE

Proc Type : Central Master Agreement

Date issued	Solicitation Closes	Solicitation Response	Version
	2016-10-20 13:30:00	SR 0608 ESR10201600000001788	1

VENDOR

000000221536

REDWOOD TOXICOLOGY LABORATORY INC

Solicitation Number: CRFQ 0608 COR1700000001

Total Bid : $769,076.00 **Response Date:** 2016-10-20 **Response Time:** 12:42:48

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	Narcotic test kits - Inmate and Parolees	2000.00000	EA	$2.290000	$4,580.00

Comm Code	Manufacturer	Specification	Model #
46151606			

Extended Description : 6-panel

Line	Comm Ln Desc	Qty	Unit Issue	Unit Price	Ln Total Or Contract Amount
2	Narcotic test kits - Inmate and Parolees	30000.00000	EA	$2.340000	$70,200.00

Comm Code	Manufacturer	Specification	Model #
46151606			

Extended Description : 10-panel

Line	Comm Ln Desc	Qty	Unit Issue	Unit Price	Ln Total Or Contract Amount
3	Narcotic test kits - Inmate and Parolees	13000.00000	EA	$3.890000	$50,570.00

Comm Code	Manufacturer	Specification	Model #
46151606			

Extended Description : 13-panel

Line	Comm Ln Desc	Qty	Unit Issue	Unit Price	Ln Total Or Contract Amount
4	Manual swab test kits - Inmate and Parolees	5000.00000	EA	$5.400000	$27,000.00

Comm Code	Manufacturer	Specification	Model #
41112601			

Extended Description : Manual swab test kits - Inmate and Parolees

Line	Comm Ln Desc	Qty	Unit Issue	Unit Price	Ln Total Or Contract Amount
5	Narcotic test kits - Employees	100.00000	EA	$2.290000	$229.00

Comm Code	Manufacturer	Specification	Model #
46151606			

Extended Description : 6-panel

Line	Comm Ln Desc	Qty	Unit Issue	Unit Price	Ln Total Or Contract Amount
6	Narcotic test kits - Employees	100.00000	EA	$2.340000	$234.00

Comm Code	Manufacturer	Specification	Model #
46151606			

Extended Description : 10-panel

Line	Comm Ln Desc	Qty	Unit Issue	Unit Price	Ln Total Or Contract Amount
7	Narcotic test kits - Employees	100.00000	EA	$3.980000	$398.00

Comm Code	Manufacturer	Specification	Model #
46151606			

Extended Description : 13-panel

Line	Comm Ln Desc	Qty	Unit Issue	Unit Price	Ln Total Or Contract Amount
8	Manual swab test kits - Employees	100.00000	EA	$5.400000	$540.00

Comm Code	Manufacturer	Specification	Model #
41112601			

Extended Description : Manual swab test kits - Employees

Line	Comm Ln Desc	Qty	Unit Issue	Unit Price	Ln Total Or Contract Amount
9	Urinalysis laboratory services	100.00000	EA	$9.500000	$950.00

Comm Code	Manufacturer	Specification	Model #
85121805			

Extended Description : 6-panel confirmation testing

Comments: Laboratory confirmation (inmate/parole) per drug.

Line	Comm Ln Desc	Qty	Unit Issue	Unit Price	Ln Total Or Contract Amount
10	Urinalysis laboratory services	100.00000	EA	$13.000000	$1,300.00

Comm Code	Manufacturer	Specification	Model #
85121805			

Extended Description : 10-panel confirmation testing

Comments: Laboratory confirmation (employee) per drug.

Line	Comm Ln Desc	Qty	Unit Issue	Unit Price	Ln Total Or Contract Amount
11	Narcotic test kits - Inmate and Parolees	2000.00000	EA	$300.000000	$600,000.00

Comm Code	Manufacturer	Specification	Model #
46151606			

Extended Description : 6-panel

Comments: Expert Witness Testimony : Toxicologist - $300/hour including travel with a per day maximum of $1000.00. MRO services not provided

Line	Comm Ln Desc	Qty	Unit Issue	Unit Price	Ln Total Or Contract Amount
12	Training	1.00000	EA	$0.000000	$0.00

Comm Code	Manufacturer	Specification	Model #
46151606			

Extended Description : In person training course for DOC employees

Line	Comm Ln Desc	Qty	Unit Issue	Unit Price	Ln Total Or Contract Amount
13	Emergency Delivery Order	1.00000	EA	$50.000000	$50.00

Comm Code	Manufacturer	Specification	Model #
46151606			

Extended Description : Emergency Delivery Order

Line	Comm Ln Desc	Qty	Unit Issue	Unit Price	Ln Total Or Contract Amount
14	Shipping Charge	1.00000	EA	$25.000000	$25.00

Comm Code	Manufacturer	Specification	Model #
46151606			

Extended Description : Shipping charge (less than 5 specimens per delivery)

Line	Comm Ln Desc	Qty	Unit Issue	Unit Price	Ln Total Or Contract Amount
15	EtG and EtS Testing	1000.00000	EA	$13.000000	$13,000.00

Comm Code	Manufacturer	Specification	Model #
46151606			

Extended Description : EtG and EtS Testing

REDWOOD TOXICOLOGY LABORATORY

Confidence in testing.

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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: 238214
Doc Description: ADDENDUM 5 DRUG TEST KITS- INMATES, PAROLEES, AND EMPLOYEE
Proc Type: Central Master Agreement

Date Issued	Solicitation Closes	Solicitation No	Version
2016-10-07	2016-10-20 13:30:00	CRFQ 0608 COR1700000001	6

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, Inc
3650 Westwind Blvd
Santa Rosa, CA 95403
800-255-2159

FOR INFORMATION CONTACT THE BUYER

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

Signature X **FEIN #** 68-0332937 **DATE** 10-17-2016

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

ADDITIONAL INFORMAITON:

Addendum No. 5 -

To extend the bid opening date to 10/20/2016 at 1:30 PM EST

INVOICE TO	SHIP TO
VARIOUS AGENCY LOCATIONS AS INDICATED BY ORDER	STATE OF WEST VIRGINIA VARIOUS LOCATIONS AS INDICATED BY ORDER
No City WV99999	No City WV 99999
US	US

Line	Comm Ln Desc	Qty	Unit Issue	Unit Price	Total Price
1	Narcotic test kits - Inmate and Parolees	2000.00000	EA	$2.29	$4,580.00

Comm Code	Manufacturer	Specification	Model #
46151606	ALERE	ICup	011022038

Extended Description :
6-panel

INVOICE TO	SHIP TO
VARIOUS AGENCY LOCATIONS AS INDICATED BY ORDER	STATE OF WEST VIRGINIA VARIOUS LOCATIONS AS INDICATED BY ORDER
No City WV99999	No City WV 99999
US	US

Line	Comm Ln Desc	Qty	Unit Issue	Unit Price	Total Price
2	Narcotic test kits - Inmate and Parolees	30000.00000	EA	$2.34	$70,200.00

Comm Code	Manufacturer	Specification	Model #
46151606	ALERE	ICup	011022129

Extended Description :
10-panel

INVOICE TO	SHIP TO
VARIOUS AGENCY LOCATIONS AS INDICATED BY ORDER	STATE OF WEST VIRGINIA VARIOUS LOCATIONS AS INDICATED BY ORDER
No City WV99999	No City WV 99999
US	US

Line	Comm Ln Desc	Qty	Unit Issue	Unit Price	Total Price
3	Narcotic test kits - Inmate and Parolees	13000.00000	EA	$3.89	$50,570.00

Comm Code	Manufacturer	Specification	Model #
46151606	ALERE	ICup	015770202

Extended Description :
13-panel

INVOICE TO	SHIP TO
VARIOUS AGENCY LOCATIONS AS INDICATED BY ORDER No City WV99999 US	STATE OF WEST VIRGINIA VARIOUS LOCATIONS AS INDICATED BY ORDER No City WV 99999 US

Line	Comm Ln Desc	Qty	Unit Issue	Unit Price	Total Price
4	Manual swab test kits - Inmate and Parolees	5000.00000	EA	$5.40	$ 27,000.00

Comm Code	Manufacturer	Specification	Model #
41112601	US Diagnostics	UScreen Oral Fluid	015010006

Extended Description :
Manual swab test kits - Inmate and Parolees

INVOICE TO	SHIP TO
VARIOUS AGENCY LOCATIONS AS INDICATED BY ORDER No City WV99999 US	STATE OF WEST VIRGINIA VARIOUS LOCATIONS AS INDICATED BY ORDER No City WV 99999 US

Line	Comm Ln Desc	Qty	Unit Issue	Unit Price	Total Price
5	Narcotic test kits - Employees	100.00000	EA	$2.29	$229.00

Comm Code	Manufacturer	Specification	Model #
46151606	ALERE	ICup	011022038

Extended Description :
6-panel

INVOICE TO	SHIP TO
VARIOUS AGENCY LOCATIONS AS INDICATED BY ORDER No City WV99999 US	STATE OF WEST VIRGINIA VARIOUS LOCATIONS AS INDICATED BY ORDER No City WV 99999 US

Line	Comm Ln Desc	Qty	Unit Issue	Unit Price	Total Price
6	Narcotic test kits - Employees	100.00000	EA	$2.34	$234.00

Comm Code	Manufacturer	Specification	Model #
46151606	ALERE	ICup	011022129

Extended Description :
10-panel

INVOICE TO	SHIP TO
VARIOUS AGENCY LOCATIONS AS INDICATED BY ORDER No City WV99999 US	STATE OF WEST VIRGINIA VARIOUS LOCATIONS AS INDICATED BY ORDER No City WV 99999 US

Line	Comm Ln Desc	Qty	Unit Issue	Unit Price	Total Price
7	Narcotic test kits - Employees	100.00000	EA	$3.89	$389.00

Comm Code	Manufacturer	Specification	Model #
46151606	ALERE	ICup	015770202

Extended Description :
13-panel

INVOICE TO	SHIP TO
VARIOUS AGENCY LOCATIONS AS INDICATED BY ORDER No City WV99999 US	STATE OF WEST VIRGINIA VARIOUS LOCATIONS AS INDICATED BY ORDER No City WV 99999 US

Line	Comm Ln Desc	Qty	Unit Issue	Unit Price	Total Price
8	Manual swab test kits - Employees	100.00000	EA	$5.40	$ 27,000.00

Comm Code	Manufacturer	Specification	Model #
41112601	US Diagnostics	UScreen Oral Fluid	015010006

Extended Description :
Manual swab test kits - Employees

INVOICE TO	SHIP TO
VARIOUS AGENCY LOCATIONS AS INDICATED BY ORDER No City WV99999 US	STATE OF WEST VIRGINIA VARIOUS LOCATIONS AS INDICATED BY ORDER No City WV 99999 US

Line	Comm Ln Desc	Qty	Unit Issue	Unit Price	Total Price
9	Urinalysis laboratory services	100.00000	EA	$9.50	$950.00

Comm Code	Manufacturer	Specification	Model #
85121805	Confirmation test pricing is per drug confirmed for Inmate / Parole.		

Extended Description :
6-panel confirmation testing

INVOICE TO	SHIP TO
VARIOUS AGENCY LOCATIONS AS INDICATED BY ORDER No City WV99999 US	STATE OF WEST VIRGINIA VARIOUS LOCATIONS AS INDICATED BY ORDER No City WV 99999 US

Line	Comm Ln Desc	Qty	Unit Issue	Unit Price	Total Price
10	Urinalysis laboratory services	100.00000	EA	$13.00	$1300.00

Comm Code	Manufacturer	Specification	Model #
85121805	Confirmation test pricing is per drug confirmed for Employee.		

Extended Description :
10-panel confirmation testing

INVOICE TO	SHIP TO
VARIOUS AGENCY LOCATIONS AS INDICATED BY ORDER No City WV99999 US	STATE OF WEST VIRGINIA VARIOUS LOCATIONS AS INDICATED BY ORDER No City WV 99999 US

Line	Comm Ln Desc	Qty	Unit Issue	Unit Price	Total Price
11	~~Narcotic test kits - Inmate and Parolees~~ Expert Witness	~~2000.00000~~	EA	$300.00 / HR	$300.00 / HR

Comm Code	Manufacturer	Specification	Model #
46151606	$300/HR including travel with a per day max of $1000.00		

Extended Description :

~~6-panel~~ Expert Witness

INVOICE TO	SHIP TO
VARIOUS AGENCY LOCATIONS AS INDICATED BY ORDER No City WV99999 US	STATE OF WEST VIRGINIA VARIOUS LOCATIONS AS INDICATED BY ORDER No City WV 99999 US

Line	Comm Ln Desc	Qty	Unit Issue	Unit Price	Total Price
12	Training	1.00000	EA	$0.00	$0.00

Comm Code	Manufacturer	Specification	Model #
46151606	RTL provides Online modules, webinar and on location training free of charge.		

Extended Description :

In person training course for DOC employees

INVOICE TO	SHIP TO
VARIOUS AGENCY LOCATIONS AS INDICATED BY ORDER No City WV99999 US	STATE OF WEST VIRGINIA VARIOUS LOCATIONS AS INDICATED BY ORDER No City WV 99999 US

Line	Comm Ln Desc	Qty	Unit Issue	Unit Price	Total Price
13	Emergency Delivery Order	1.00000	EA	$50.00	$50.00

Comm Code	Manufacturer	Specification	Model #
46151606	RTL will process and ship emergency orders to the state with in 2 business days of receipt of order.		

Extended Description :
Emergency Delivery Order

INVOICE TO	SHIP TO
VARIOUS AGENCY LOCATIONS AS INDICATED BY ORDER No City WV99999 US	STATE OF WEST VIRGINIA VARIOUS LOCATIONS AS INDICATED BY ORDER No City WV 99999 US

Line	Comm Ln Desc	Qty	Unit Issue	Unit Price	Total Price
14	Shipping Charge	1.00000	EA	$25.00	$25.00

Comm Code	Manufacturer	Specification	Model #
46151606			

Extended Description :
Shipping charge (less than 5 specimens per delivery)

INVOICE TO	SHIP TO
VARIOUS AGENCY LOCATIONS AS INDICATED BY ORDER No City WV99999 US	STATE OF WEST VIRGINIA VARIOUS LOCATIONS AS INDICATED BY ORDER No City WV 99999 US

Line	Comm Ln Desc	Qty	Unit Issue	Unit Price	Total Price
15	EtG and EtS Testing	1000.00000	EA	$12.00	$12,000.00

Comm Code	Manufacturer	Specification	Model #
46151606		EtG Lab screen + Confirmation	

Extended Description :
EtG and EtS Testing

SCHEDULE OF EVENTS

Line	Event	Event Date
1	VENDOR QUESTION DEADLINE	2016-08-29

INSTRUCTIONS TO VENDORS SUBMITTING BIDS

1. REVIEW DOCUMENTS THOROUGHLY: The attached documents contain a solicitation for bids. Please read these instructions and all documents attached in their entirety. These instructions provide critical information about requirements that if overlooked could lead to disqualification of a Vendor's bid. All bids must be submitted in accordance with the provisions contained in these instructions and the Solicitation. Failure to do so may result in disqualification of Vendor's bid.

2. MANDATORY TERMS: The Solicitation may contain mandatory provisions identified by the use of the words "must," "will," and "shall." Failure to comply with a mandatory term in the Solicitation will result in bid disqualification.

3. PREBID MEETING: The item identified below shall apply to this Solicitation.

☑ A pre-bid meeting will not be held prior to bid opening

☐ A **NON-MANDATORY PRE-BID** meeting will be held at the following place and time:

☐ A **MANDATORY PRE-BID** meeting will be held at the following place and time:

All Vendors submitting a bid must attend the mandatory pre-bid meeting. Failure to attend the mandatory pre-bid meeting shall result in disqualification of the Vendor's bid. No one person attending the pre-bid meeting may represent more than one Vendor.

An attendance sheet provided at the pre-bid meeting shall serve as the official document verifying attendance. The State will not accept any other form of proof or documentation to verify attendance. Any person attending the pre-bid meeting on behalf of a Vendor must list on the attendance sheet his or her name and the name of the Vendor he or she is representing.

Additionally, the person attending the pre-bid meeting should include the Vendor's E-Mail address, phone number, and Fax number on the attendance sheet. It is the Vendor's responsibility to locate the attendance sheet and provide the required information. Failure to complete the attendance sheet as required may result in disqualification of Vendor's bid.

All Vendors should arrive prior to the starting time for the pre-bid. Vendors who arrive after the starting time but prior to the end of the pre-bid will be permitted to sign in, but are charged with knowing all matters discussed at the pre-bid.

Questions submitted at least five business days prior to a scheduled pre-bid will be discussed at the pre-bid meeting if possible. Any discussions or answers to questions at the pre-bid meeting are preliminary in nature and are non-binding. Official and binding answers to questions will be published in a written addendum to the Solicitation prior to bid opening.

4. VENDOR QUESTION DEADLINE: Vendors may submit questions relating to this Solicitation to the Purchasing Division. Questions must be submitted in writing. All questions must be submitted on or before the date listed below and to the address listed below in order to be considered. A written response will be published in a Solicitation addendum if a response is possible and appropriate. Non-written discussions, conversations, or questions and answers regarding this Solicitation are preliminary in nature and are nonbinding.

Submitted e-mails should have solicitation number in the subject line.

Question Submission Deadline: August 29, 2016 at 4:00 PM EST

Submit Questions to: Crystal Rink
2019 Washington Street, East
Charleston, WV 25305
Fax: (304) 558-4115 (Vendors should not use this fax number for bid submission)
Email: Crystal.G.Rink@wv.gov

5. VERBAL COMMUNICATION: Any verbal communication between the Vendor and any State personnel is not binding, including verbal communication at the mandatory pre-bid conference. Only information issued in writing and added to the Solicitation by an official written addendum by the Purchasing Division is binding.

6. BID SUBMISSION: All bids must be submitted electronically through wvOASIS or signed and delivered by the Vendor to the Purchasing Division at the address listed below on or before the date and time of the bid opening. Any bid received by the Purchasing Division staff is considered to be in the possession of the Purchasing Division and will not be returned for any reason. The Purchasing Division will not accept bids, modification of bids, or addendum acknowledgment forms via e-mail. Acceptable delivery methods include electronic submission via wvOASIS, hand delivery, delivery by courier, or facsimile.

The bid delivery address is:
Department of Administration, Purchasing Division
2019 Washington Street East
Charleston, WV 25305-0130

A bid that is not submitted electronically through wvOASIS should contain the information listed below on the face of the envelope or the bid may be rejected by the Purchasing Division.:

SEALED BID:
BUYER: Crystal Rink
SOLICITATION NO.: CRFQ COR1700000001
BID OPENING DATE: September 15, 2016
BID OPENING TIME: 1:30 PM EST
FAX NUMBER: 304-558-3970

The Purchasing Division may prohibit the submission of bids electronically through wvOASIS at its sole discretion. Such a prohibition will be contained and communicated in the wvOASIS system resulting in the Vendor's inability to submit bids through wvOASIS. Submission of a response to an Expression or Interest or Request for Proposal is not permitted in wvOASIS.

For Request For Proposal ("RFP") Responses Only: In the event that Vendor is responding to a request for proposal, the Vendor shall submit one original technical and one original cost proposal plus n/a convenience copies of each to the Purchasing Division at the address shown above. Additionally, the Vendor should identify the bid type as either a technical or cost proposal on the face of each bid envelope submitted in response to a request for proposal as follows:

BID TYPE: (This only applies to CRFP)
☐ Technical
☐ Cost

7. BID OPENING: Bids submitted in response to this Solicitation will be opened at the location identified below on the date and time listed below. Delivery of a bid after the bid opening date and time will result in bid disqualification. For purposes of this Solicitation, a bid is considered delivered when confirmation of delivery is provided by wvOASIS (in the case of electronic submission) or when the bid is time stamped by the official Purchasing Division time clock (in the case of hand delivery).

Bid Opening Date and Time: September 15, 2016 at 1:30 PM EST

Bid Opening Location: Department of Administration, Purchasing Division
2019 Washington Street East
Charleston, WV 25305-0130

8. ADDENDUM ACKNOWLEDGEMENT: Changes or revisions to this Solicitation will be made by an official written addendum issued by the Purchasing Division. Vendor should acknowledge receipt of all addenda issued with this Solicitation by completing an Addendum Acknowledgment Form, a copy of which is included herewith. Failure to acknowledge addenda may result in bid disqualification. The addendum acknowledgement should be submitted with the bid to expedite document processing.

9. BID FORMATTING: Vendor should type or electronically enter the information onto its bid to prevent errors in the evaluation. Failure to type or electronically enter the information may result in bid disqualification.

10. ALTERNATES: Any model, brand, or specification listed in this Solicitation establishes the acceptable level of quality only and is not intended to reflect a preference for, or in any way favor, a particular brand or vendor. Vendors may bid alternates to a listed model or brand provided that the alternate is at least equal to the model or brand and complies with the required specifications. The equality of any alternate being bid shall be determined by the State at its sole discretion. Any Vendor bidding an alternate model or brand should clearly identify the alternate items in its bid and should include manufacturer's specifications, industry literature, and/or any other relevant documentation demonstrating the equality of the alternate items. Failure to provide information for alternate items may be grounds for rejection of a Vendor's bid.

11. EXCEPTIONS AND CLARIFICATIONS: The Solicitation contains the specifications that shall form the basis of a contractual agreement. Vendor shall clearly mark any exceptions, clarifications, or other proposed modifications in its bid. Exceptions to, clarifications of, or modifications of a requirement or term and condition of the Solicitation may result in bid disqualification.

12. COMMUNICATION LIMITATIONS: In accordance with West Virginia Code of State Rules §148-1-6.6, communication with the State of West Virginia or any of its employees regarding this Solicitation during the solicitation, bid, evaluation or award periods, except through the Purchasing Division, is strictly prohibited without prior Purchasing Division approval. Purchasing Division approval for such communication is implied for all agency delegated and exempt purchases.

13. REGISTRATION: Prior to Contract award, the apparent successful Vendor must be properly registered with the West Virginia Purchasing Division and must have paid the $125 fee, if applicable.

14. UNIT PRICE: Unit prices shall prevail in cases of a discrepancy in the Vendor's bid.

15. PREFERENCE: Vendor Preference may only be granted upon written request and only in accordance with the West Virginia Code § 5A-3-37 and the West Virginia Code of State Rules. A Vendor Preference Certificate form has been attached hereto to allow Vendor to apply for the preference. Vendor's failure to submit the Vendor Preference Certificate form with its bid will result in denial of Vendor Preference. Vendor Preference does not apply to construction projects.

16. SMALL, WOMEN-OWNED, OR MINORITY-OWNED BUSINESSES: For any solicitations publicly advertised for bid, in accordance with West Virginia Code §5A-3-37(a)(7) and W. Va. CSR § 148-22-9, any non-resident vendor certified as a small, women-owned, or minority-owned business under W. Va. CSR § 148-22-9 shall be provided the same preference made available to any resident vendor. Any non-resident small, women-owned, or minority-owned business must identify itself as such in writing, must submit that writing to the Purchasing Division with its bid, and must be properly certified under W. Va. CSR § 148-22-9 prior to contract award to receive the preferences made available to resident vendors. Preference for a non-resident small, women-owned, or minority owned business shall be applied in accordance with W. Va. CSR § 148-22-9.

17. WAIVER OF MINOR IRREGULARITIES: The Director reserves the right to waive minor irregularities in bids or specifications in accordance with West Virginia Code of State Rules § 148-1-4.6.

18. ELECTRONIC FILE ACCESS RESTRICTIONS: Vendor must ensure that its submission in wvOASIS can be accessed by the Purchasing Division staff immediately upon bid opening. The Purchasing Division will consider any file that cannot be immediately opened and/or viewed at the time of the bid opening (such as, encrypted files, password protected files, or incompatible files) to be blank or incomplete as context requires, and are therefore unacceptable. A vendor will not be permitted to unencrypt files, remove password protections, or resubmit documents after bid opening if those documents are required with the bid.

19. NON-RESPONSIBLE: The Purchasing Division Director reserves the right to reject the bid of any vendor as Non-Responsible in accordance with W. Va. Code of State Rules § 148-1-5.3, when the Director determines that the vendor submitting the bid does not have the capability to fully perform, or lacks the integrity and reliability to assure good-faith performance."

20. ACCEPTANCE/REJECTION: The State may accept or reject any bid in whole, or in part in accordance with W. Va. Code of State Rules § 148-1-4.5. and § 148-1-6.4.b."

21. YOUR SUBMISSION IS A PUBLIC DOCUMENT: Vendor's entire response to the Solicitation and the resulting Contract are public documents. As public documents, they will be disclosed to the public following the bid/proposal opening or award of the contract, as required by the competitive bidding laws of West Virginia Code §§ 5A-3-1 et seq., 5-22-1 et seq., and 5G-1-1 et seq. and the Freedom of Information Act West Virginia Code §§ 29B-1-1 et seq.

DO NOT SUBMIT MATERIAL YOU CONSIDER TO BE CONFIDENTIAL, A TRADE SECRET, OR OTHERWISE NOT SUBJECT TO PUBLIC DISCLOSURE.

Submission of any bid, proposal, or other document to the Purchasing Division constitutes your explicit consent to the subsequent public disclosure of the bid, proposal, or document. The Purchasing Division will disclose any document labeled "confidential," "proprietary," "trade secret," "private," or labeled with any other claim against public disclosure of the documents, to include any "trade secrets" as defined by West Virginia Code § 47-22-1 et seq. All submissions are subject to public disclosure without notice.

GENERAL TERMS AND CONDITIONS:

1. CONTRACTUAL AGREEMENT: Issuance of a Award Document signed by the Purchasing Division Director, or his designee, and approved as to form by the Attorney General's office constitutes acceptance of this Contract made by and between the State of West Virginia and the Vendor. Vendor's signature on its bid signifies Vendor's agreement to be bound by and accept the terms and conditions contained in this Contract.

2. DEFINITIONS: As used in this Solicitation/Contract, the following terms shall have the meanings attributed to them below. Additional definitions may be found in the specifications included with this Solicitation/Contract.

2.1. "Agency" or **"Agencies"** means the agency, board, commission, or other entity of the State of West Virginia that is identified on the first page of the Solicitation or any other public entity seeking to procure goods or services under this Contract.

2.2. "Bid" or **"Proposal"** means the vendors submitted response to this solicitation.

2.3. "Contract" means the binding agreement that is entered into between the State and the Vendor to provide the goods or services requested in the Solicitation.

2.4. "Director" means the Director of the West Virginia Department of Administration, Purchasing Division.

2.5. "Purchasing Division" means the West Virginia Department of Administration, Purchasing Division.

2.6. "Award Document" means the document signed by the Agency and the Purchasing Division, and approved as to form by the Attorney General, that identifies the Vendor as the contract holder.

2.7. "Solicitation" means the official notice of an opportunity to supply the State with goods or services that is published by the Purchasing Division.

2.8. "State" means the State of West Virginia and/or any of its agencies, commissions, boards, etc. as context requires.

2.9. "Vendor" or **"Vendors"** means any entity submitting a bid in response to the Solicitation, the entity that has been selected as the lowest responsible bidder, or the entity that has been awarded the Contract as context requires.

3. CONTRACT TERM; RENEWAL; EXTENSION: The term of this Contract shall be determined in accordance with the category that has been identified as applicable to this Contract below:

☑ **Term Contract**

Initial Contract Term: This Contract becomes effective on award and extends for a period of one (1) year(s).

Renewal Term: This Contract may be renewed upon the mutual written consent of the Agency, and the Vendor, with approval of the Purchasing Division and the Attorney General's office (Attorney General approval is as to form only). Any request for renewal should be submitted to the Purchasing Division thirty (30) days prior to the expiration date of the initial contract term or appropriate renewal term. A Contract renewal shall be in accordance with the terms and conditions of the original contract. Renewal of this Contract is limited to three (3) successive one (1) year periods or multiple renewal periods of less than one year, provided that the multiple renewal periods do not exceed thirty-six (36) months in total. Automatic renewal of this Contract is prohibited. Notwithstanding the foregoing, Purchasing Division approval is not required on agency delegated or exempt purchases. Attorney General approval may be required for vendor terms and conditions.

Delivery Order Limitations: In the event that this contract permits delivery orders, a delivery order may only be issued during the time this Contract is in effect. Any delivery order issued within one year of the expiration of this Contract shall be effective for one year from the date the delivery order is issued. No delivery order may be extended beyond one year after this Contract has expired.

☐ **Fixed Period Contract:** This Contract becomes effective upon Vendor's receipt of the notice to proceed and must be completed within _____ days.

☐ **Fixed Period Contract with Renewals:** This Contract becomes effective upon Vendor's receipt of the notice to proceed and part of the Contract more fully described in the attached specifications must be completed within _____ days.

Upon completion, the vendor agrees that maintenance, monitoring, or warranty services will be provided for one year thereafter with an additional _____ successive one year renewal periods or multiple renewal periods of less than one year provided that the multiple renewal periods do not exceed _____ months in total. Automatic renewal of this Contract is prohibited.

☐ **One Time Purchase:** The term of this Contract shall run from the issuance of the Award Document until all of the goods contracted for have been delivered, but in no event will this Contract extend for more than one fiscal year.

☐ **Other:** See attached.

4. NOTICE TO PROCEED: Vendor shall begin performance of this Contract immediately upon receiving notice to proceed unless otherwise instructed by the Agency. Unless otherwise specified, the fully executed Award Document will be considered notice to proceed.

5. QUANTITIES: The quantities required under this Contract shall be determined in accordance with the category that has been identified as applicable to this Contract below.

☑ **Open End Contract:** Quantities listed in this Solicitation are approximations only, based on estimates supplied by the Agency. It is understood and agreed that the Contract shall cover the quantities actually ordered for delivery during the term of the Contract, whether more or less than the quantities shown.

☐ **Service:** The scope of the service to be provided will be more clearly defined in the specifications included herewith.

☐ **Combined Service and Goods:** The scope of the service and deliverable goods to be provided will be more clearly defined in the specifications included herewith.

☐ **One Time Purchase:** This Contract is for the purchase of a set quantity of goods that are identified in the specifications included herewith. Once those items have been delivered, no additional goods may be procured under this Contract without an appropriate change order approved by the Vendor, Agency, Purchasing Division, and Attorney General's office.

6. EMERGENCY PURCHASES: The Purchasing Division Director may authorize the Agency to purchase goods or services in the open market that Vendor would otherwise provide under this Contract if those goods or services are for immediate or expedited delivery in an emergency. Emergencies shall include, but are not limited to, delays in transportation or an unanticipated increase in the volume of work. An emergency purchase in the open market, approved by the Purchasing Division Director, shall not constitute of breach of this Contract and shall not entitle the Vendor to any form of compensation or damages. This provision does not excuse the State from fulfilling its obligations under a One Time Purchase contract.

7. REQUIRED DOCUMENTS: All of the items checked below must be provided to the Purchasing Division by the Vendor as specified below.

☐ **BID BOND (Construction Only):** Pursuant to the requirements contained in W. Va. Code § 5-22-1(c), All Vendors submitting a bid on a construction project shall furnish a valid bid bond in the amount of five percent (5%) of the total amount of the bid protecting the State of West Virginia. The bid bond must be submitted with the bid.

☐ **PERFORMANCE BOND:** The apparent successful Vendor shall provide a performance bond in the amount of _____. The performance bond must be received by the Purchasing Division prior to Contract award. On construction contracts, the performance bond must be 100% of the Contract value.

☐ **LABOR/MATERIAL PAYMENT BOND:** The apparent successful Vendor shall provide a labor/material payment bond in the amount of 100% of the Contract value. The labor/material payment bond must be delivered to the Purchasing Division prior to Contract award.
In lieu of the Bid Bond, Performance Bond, and Labor/Material Payment Bond, the Vendor may provide certified checks, cashier's checks, or irrevocable letters of credit. Any certified check, cashier's check, or irrevocable letter of credit provided in lieu of a bond must be of the same amount and delivered on the same schedule as the bond it replaces. A letter of credit submitted in lieu of a performance and labor/material payment bond will only be allowed for projects under $100,000. Personal or business checks are not acceptable.

☐ **MAINTENANCE BOND:** The apparent successful Vendor shall provide a two (2) year maintenance bond covering the roofing system. The maintenance bond must be issued and delivered to the Purchasing Division prior to Contract award.

☐ **INSURANCE:** The apparent successful Vendor shall furnish proof of the following insurance prior to Contract award and shall list the state as a certificate holder:

☐ **Commercial General Liability Insurance:** In the amount of _____ _____ or more.

☐ **Builders Risk Insurance:** In an amount equal to 100% of the amount of the Contract.

☐

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☐

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The apparent successful Vendor shall also furnish proof of any additional insurance requirements contained in the specifications prior to Contract award regardless of whether or not that insurance requirement is listed above.

☐ **LICENSE(S) / CERTIFICATIONS / PERMITS:** In addition to anything required under the Section entitled Licensing, of the General Terms and Conditions, the apparent successful Vendor shall furnish proof of the following licenses, certifications, and/or permits prior to Contract award, in a form acceptable to the Purchasing Division.

☐

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The apparent successful Vendor shall also furnish proof of any additional licenses or certifications contained in the specifications prior to Contract award regardless of whether or not that requirement is listed above.

8. WORKERS' COMPENSATION INSURANCE: The apparent successful Vendor shall comply with laws relating to workers compensation, shall maintain workers' compensation insurance when required, and shall furnish proof of workers' compensation insurance upon request.

9. LITIGATION BOND: The Director reserves the right to require any Vendor that files a protest of an award to submit a litigation bond in the amount equal to one percent of the lowest bid submitted or $5,000, whichever is greater. The entire amount of the bond shall be forfeited if the hearing officer determines that the protest was filed for frivolous or improper purpose, including but not limited to, the purpose of harassing, causing unnecessary delay, or needless expense for the Agency. All litigation bonds shall be made payable to the Purchasing Division. In lieu of a bond, the protester may submit a cashier's check or certified check payable to the Purchasing Division. Cashier's or certified checks will be deposited with and held by the State Treasurer's office. If it is determined that the protest has not been filed for frivolous or improper purpose, the bond or deposit shall be returned in its entirety.

10. LIQUIDATED DAMAGES: Vendor shall pay liquidated damages in the amount of n/a
for n/a.
This clause shall in no way be considered exclusive and shall not limit the State or Agency's right to pursue any other available remedy.

11. ACCEPTANCE: Vendor's signature on its bid, or on the certification and signature page, constitutes an offer to the State that cannot be unilaterally withdrawn, signifies that the product or service proposed by vendor meets the mandatory requirements contained in the Solicitation for that product or service, unless otherwise indicated, and signifies acceptance of the terms and conditions contained in the Solicitation unless otherwise indicated.

12. PRICING: The pricing set forth herein is firm for the life of the Contract, unless specified elsewhere within this Solicitation/Contract by the State. A Vendor's inclusion of price adjustment provisions in its bid, without an express authorization from the State in the Solicitation to do so, may result in bid disqualification.

13. PAYMENT: Payment in advance is prohibited under this Contract. Payment may only be made after the delivery and acceptance of goods or services. The Vendor shall submit invoices, in arrears.

14. PURCHASING CARD ACCEPTANCE: The State of West Virginia currently utilizes a Purchasing Card program, administered under contract by a banking institution, to process payment for goods and services. The Vendor must accept the State of West Virginia's Purchasing Card for payment of all orders under this Contract unless the box below is checked.

☐ Vendor is not required to accept the State of West Virginia's Purchasing Card as payment for all goods and services.

15. TAXES: The Vendor shall pay any applicable sales, use, personal property or any other taxes arising out of this Contract and the transactions contemplated thereby. The State of West Virginia is exempt from federal and state taxes and will not pay or reimburse such taxes.

16. ADDITIONAL FEES: Vendor is not permitted to charge additional fees or assess additional charges that were not either expressly provided for in the solicitation published by the State of West Virginia or included in the unit price or lump sum bid amount that Vendor is required by the solicitation to provide. Including such fees or charges as notes to the solicitation may result in rejection of vendor's bid. Requesting such fees or charges be paid after the contract has been awarded may result in cancellation of the contract.

17. FUNDING: This Contract shall continue for the term stated herein, contingent upon funds being appropriated by the Legislature or otherwise being made available. In the event funds are not appropriated or otherwise made available, this Contract becomes void and of no effect beginning on July 1 of the fiscal year for which funding has not been appropriated or otherwise made available.

18. CANCELLATION: The Purchasing Division Director reserves the right to cancel this Contract immediately upon written notice to the vendor if the materials or workmanship supplied do not conform to the specifications contained in the Contract. The Purchasing Division Director may also cancel any purchase or Contract upon 30 days written notice to the Vendor in accordance with West Virginia Code of State Rules § 148-1-6.1.e.

19. TIME: Time is of the essence with regard to all matters of time and performance in this Contract.

20. APPLICABLE LAW: This Contract is governed by and interpreted under West Virginia law without giving effect to its choice of law principles. Any information provided in specification manuals, or any other source, verbal or written, which contradicts or violates the West Virginia Constitution, West Virginia Code or West Virginia Code of State Rules is void and of no effect.

21. COMPLIANCE: Vendor shall comply with all applicable federal, state, and local laws, regulations and ordinances. By submitting a bid, Vendor acknowledges that it has reviewed, understands, and will comply with all applicable laws, regulations, and ordinances.

22. ARBITRATION: Any references made to arbitration contained in this Contract, Vendor's bid, or in any American Institute of Architects documents pertaining to this Contract are hereby deleted, void, and of no effect.

23. MODIFICATIONS: This writing is the parties' final expression of intent. Notwithstanding anything contained in this Contract to the contrary no modification of this Contract shall be binding without mutual written consent of the Agency, and the Vendor, with approval of the Purchasing Division and the Attorney General's office (Attorney General approval is as to form only). Any change to existing contracts that adds work or changes contract cost, and were not included in the original contract, must be approved by the Purchasing Division and the Attorney General's Office (as to form) prior to the implementation of the change or commencement of work affected by the change.

24. WAIVER: The failure of either party to insist upon a strict performance of any of the terms or provision of this Contract, or to exercise any option, right, or remedy herein contained, shall not be construed as a waiver or a relinquishment for the future of such term, provision, option, right, or remedy, but the same shall continue in full force and effect. Any waiver must be expressly stated in writing and signed by the waiving party.

25. SUBSEQUENT FORMS: The terms and conditions contained in this Contract shall supersede any and all subsequent terms and conditions which may appear on any form documents submitted by Vendor to the Agency or Purchasing Division such as price lists, order forms, invoices, sales agreements, or maintenance agreements, and includes internet websites or other electronic documents. Acceptance or use of Vendor's forms does not constitute acceptance of the terms and conditions contained thereon.

26. ASSIGNMENT: Neither this Contract nor any monies due, or to become due hereunder, may be assigned by the Vendor without the express written consent of the Agency, the Purchasing Division, the Attorney General's office (as to form only), and any other government agency or office that may be required to approve such assignments. Notwithstanding the foregoing, Purchasing Division approval may or may not be required on certain agency delegated or exempt purchases.

27. WARRANTY: The Vendor expressly warrants that the goods and/or services covered by this Contract will: (a) conform to the specifications, drawings, samples, or other description furnished or specified by the Agency; (b) be merchantable and fit for the purpose intended; and (c) be free from defect in material and workmanship.

28. STATE EMPLOYEES: State employees are not permitted to utilize this Contract for personal use and the Vendor is prohibited from permitting or facilitating the same.

29. BANKRUPTCY: In the event the Vendor files for bankruptcy protection, the State of West Virginia may deem this Contract null and void, and terminate this Contract without notice.

30. PRIVACY, SECURITY, AND CONFIDENTIALITY: The Vendor agrees that it will not disclose to anyone, directly or indirectly, any such personally identifiable information or other confidential information gained from the Agency, unless the individual who is the subject of the information consents to the disclosure in writing or the disclosure is made pursuant to the Agency's policies, procedures, and rules. Vendor further agrees to comply with the Confidentiality Policies and Information Security Accountability Requirements, set forth in http://www.state.wv.us/admin/purchase/privacy/default.html.

31. YOUR SUBMISSION IS A PUBLIC DOCUMENT: Vendor's entire response to the Solicitation and the resulting Contract are public documents. As public documents, they will be disclosed to the public following the bid/proposal opening or award of the contract, as required by the competitive bidding laws of West Virginia Code §§ 5A-3-1 et seq., 5-22-1 et seq., and 5G-1-1 et seq. and the Freedom of Information Act West Virginia Code §§ 29B-1-1 et seq.

DO NOT SUBMIT MATERIAL YOU CONSIDER TO BE CONFIDENTIAL, A TRADE SECRET, OR OTHERWISE NOT SUBJECT TO PUBLIC DISCLOSURE.

Submission of any bid, proposal, or other document to the Purchasing Division constitutes your explicit consent to the subsequent public disclosure of the bid, proposal, or document. The Purchasing Division will disclose any document labeled "confidential," "proprietary," "trade secret," "private," or labeled with any other claim against public disclosure of the documents, to include any "trade secrets" as defined by West Virginia Code § 47-22-1 et seq. All submissions are subject to public disclosure without notice.

32. LICENSING: In accordance with West Virginia Code of State Rules § 148-1-6.1.e, Vendor must be licensed and in good standing in accordance with any and all state and local laws and requirements by any state or local agency of West Virginia, including, but not limited to, the West Virginia Secretary of State's Office, the West Virginia Tax Department, West Virginia Insurance Commission, or any other state agency or political subdivision. Upon request, the Vendor must provide all necessary releases to obtain information to enable the Purchasing Division Director or the Agency to verify that the Vendor is licensed and in good standing with the above entities.

33. ANTITRUST: In submitting a bid to, signing a contract with, or accepting a Award Document from any agency of the State of West Virginia, the Vendor agrees to convey, sell, assign, or transfer to the State of West Virginia all rights, title, and interest in and to all causes of action it may now or hereafter acquire under the antitrust laws of the United States and the State of West Virginia for price fixing and/or unreasonable restraints of trade relating to the particular commodities or services purchased or acquired by the State of West Virginia. Such assignment shall be made and become effective at the time the purchasing agency tenders the initial payment to Vendor.

34. VENDOR CERTIFICATIONS: By signing its bid or entering into this Contract, Vendor certifies (1) that its bid or offer was made without prior understanding, agreement, or connection with any corporation, firm, limited liability company, partnership, person or entity submitting a bid or offer for the same material, supplies, equipment or services; (2) that its bid or offer is in all respects fair and without collusion or fraud; (3) that this Contract is accepted or entered into without any prior understanding, agreement, or connection to any other entity that could be considered a violation of law; and (4) that it has reviewed this Solicitation in its entirety; understands the requirements, terms and conditions, and other information contained herein.

Vendor's signature on its bid or offer also affirms that neither it nor its representatives have any interest, nor shall acquire any interest, direct or indirect, which would compromise the performance of its services hereunder. Any such interests shall be promptly presented in detail to the Agency. The individual signing this bid or offer on behalf of Vendor certifies that he or she is authorized by the Vendor to execute this bid or offer or any documents related thereto on Vendor's behalf; that he or she is authorized to bind the Vendor in a contractual relationship; and that, to the best of his or her knowledge, the Vendor has properly registered with any State agency that may require registration.

35. VENDOR RELATIONSHIP: The relationship of the Vendor to the State shall be that of an independent contractor and no principal-agent relationship or employer-employee relationship is contemplated or created by this Contract. The Vendor as an independent contractor is solely liable for the acts and omissions of its employees and agents. Vendor shall be responsible for selecting, supervising, and compensating any and all individuals employed pursuant to the terms of this Solicitation and resulting contract. Neither the Vendor, nor any employees or subcontractors of the Vendor, shall be deemed to be employees of the State for any purpose whatsoever. Vendor shall be exclusively responsible for payment of employees and contractors for all wages and salaries, taxes, withholding payments, penalties, fees, fringe benefits, professional liability insurance premiums, contributions to insurance and pension, or other deferred compensation plans, including but not limited to, Workers' Compensation and Social Security obligations, licensing fees, etc. and the filing of all necessary documents, forms, and returns pertinent to all of the foregoing.

Vendor shall hold harmless the State, and shall provide the State and Agency with a defense against any and all claims including, but not limited to, the foregoing payments, withholdings, contributions, taxes, Social Security taxes, and employer income tax returns.

36. INDEMNIFICATION: The Vendor agrees to indemnify, defend, and hold harmless the State and the Agency, their officers, and employees from and against: (1) Any claims or losses for services rendered by any subcontractor, person, or firm performing or supplying services, materials, or supplies in connection with the performance of the Contract; (2) Any claims or losses resulting to any person or entity injured or damaged by the Vendor, its officers, employees, or subcontractors by the publication, translation, reproduction, delivery, performance, use, or disposition of any data used under the Contract in a manner not authorized by the Contract, or by Federal or State statutes or regulations; and (3) Any failure of the Vendor, its officers, employees, or subcontractors to observe State and Federal laws including, but not limited to, labor and wage and hour laws.

37. PURCHASING AFFIDAVIT: In accordance with West Virginia Code § 5A-3-10a, all Vendors are required to sign, notarize, and submit the Purchasing Affidavit stating that neither the Vendor nor a related party owe a debt to the State in excess of $1,000. The affidavit must be submitted prior to award, but should be submitted with the Vendor's bid. A copy of the Purchasing Affidavit is included herewith.

38. ADDITIONAL AGENCY AND LOCAL GOVERNMENT USE: This Contract may be utilized by other agencies, spending units, and political subdivisions of the State of West Virginia; county, municipal, and other local government bodies; and school districts ("Other Government Entities"). Any extension of this Contract to the aforementioned Other Government Entities must be on the same prices, terms, and conditions as those offered and agreed to in this Contract, provided that such extension is in compliance with the applicable laws, rules, and ordinances of the Other Government Entity. If the Vendor does not wish to extend the prices, terms, and conditions of its bid and subsequent contract to the Other Government Entities, the Vendor must clearly indicate such refusal in its bid. A refusal to extend this Contract to the Other Government Entities shall not impact or influence the award of this Contract in any manner.

39. CONFLICT OF INTEREST: Vendor, its officers or members or employees, shall not presently have or acquire an interest, direct or indirect, which would conflict with or compromise the performance of its obligations hereunder. Vendor shall periodically inquire of its officers, members and employees to ensure that a conflict of interest does not arise. Any conflict of interest discovered shall be promptly presented in detail to the Agency.

40. REPORTS: Vendor shall provide the Agency and/or the Purchasing Division with the following reports identified by a checked box below:

☑ Such reports as the Agency and/or the Purchasing Division may request. Requested reports may include, but are not limited to, quantities purchased, agencies utilizing the contract, total contract expenditures by agency, etc.

☐ Quarterly reports detailing the total quantity of purchases in units and dollars, along with a listing of purchases by agency. Quarterly reports should be delivered to the Purchasing Division via email at purchasing.requisitions@wv.gov.

41. BACKGROUND CHECK: In accordance with W. Va. Code § 15-2D-3, the Director of the Division of Protective Services shall require any service provider whose employees are regularly employed on the grounds or in the buildings of the Capitol complex or who have access to sensitive or critical information to submit to a fingerprint-based state and federal background inquiry through the state repository. The service provider is responsible for any costs associated with the fingerprint-based state and federal background inquiry.

After the contract for such services has been approved, but before any such employees are permitted to be on the grounds or in the buildings of the Capitol complex or have access to sensitive or critical information, the service provider shall submit a list of all persons who will be physically present and working at the Capitol complex to the Director of the Division of Protective Services for purposes of verifying compliance with this provision. The State reserves the right to prohibit a service provider's employees from accessing sensitive or critical information or to be present at the Capitol complex based upon results addressed from a criminal background check.

Service providers should contact the West Virginia Division of Protective Services by phone at (304) 558-9911 for more information.

42. PREFERENCE FOR USE OF DOMESTIC STEEL PRODUCTS: Except when authorized by the Director of the Purchasing Division pursuant to W. Va. Code § 5A-3-56, no contractor may use or supply steel products for a State Contract Project other than those steel products made in the United States. A contractor who uses steel products in violation of this section may be subject to civil penalties pursuant to W. Va. Code § 5A-3-56. As used in this section:

a. "State Contract Project" means any erection or construction of, or any addition to, alteration of or other improvement to any building or structure, including, but not limited to, roads or highways, or the installation of any heating or cooling or ventilating plants or other equipment, or the supply of and materials for such projects, pursuant to a contract with the State of West Virginia for which bids were solicited on or after June 6, 2001.
b. "Steel Products" means products rolled, formed, shaped, drawn, extruded, forged, cast, fabricated or otherwise similarly processed, or processed by a combination of two or more or such operations, from steel made by the open heath, basic oxygen, electric furnace, Bessemer or other steel making process. The Purchasing Division Director may, in writing, authorize the use of foreign steel products if:
c. The cost for each contract item used does not exceed one tenth of one percent (.1%) of the total contract cost or two thousand five hundred dollars ($2,500.00), whichever is greater. For the purposes of this section, the cost is the value of the steel product as delivered to the project; or
d. The Director of the Purchasing Division determines that specified steel materials are not produced in the United States in sufficient quantity or otherwise are not reasonably available to meet contract requirements.

43. PREFERENCE FOR USE OF DOMESTIC ALUMINUM, GLASS, AND STEEL: In Accordance with W. Va. Code § 5-19-1 et seq., and W. Va. CSR § 148-10-1 et seq., for every contract or subcontract, subject to the limitations contained herein, for the construction, reconstruction, alteration, repair, improvement or maintenance of public works or for the purchase of any item of machinery or equipment to be used at sites of public works, only domestic aluminum, glass or steel products shall be supplied unless the spending officer determines, in writing, after the receipt of offers or bids, (1) that the cost of domestic aluminum, glass or steel products is unreasonable or inconsistent with the public interest of the State of West Virginia, (2) that domestic aluminum, glass or steel products are not produced in sufficient quantities to meet the contract requirements, or (3) the available domestic aluminum, glass, or steel do not meet the contract specifications. This provision only applies to public works contracts awarded in an amount more than fifty thousand dollars ($50,000) or public works contracts that require more than ten thousand pounds of steel products.

The cost of domestic aluminum, glass, or steel products may be unreasonable if the cost is more than twenty percent (20%) of the bid or offered price for foreign made aluminum, glass, or steel products. If the domestic aluminum, glass or steel products to be supplied or produced in a "substantial labor surplus area", as defined by the United States Department of Labor, the cost of domestic aluminum, glass, or steel products may be unreasonable if the cost is more than thirty percent (30%) of the bid or offered price for foreign made aluminum, glass, or steel products. This preference shall be applied to an item of machinery or equipment, as indicated above, when the item is a single unit of equipment or machinery manufactured primarily of aluminum, glass or steel, is part of a public works contract and has the sole purpose or of being a permanent part of a single public works project. This provision does not apply to equipment or machinery purchased by a spending unit for use by that spending unit and not as part of a single public works project.

All bids and offers including domestic aluminum, glass or steel products that exceed bid or offer prices including foreign aluminum, glass or steel products after application of the preferences provided in this provision may be reduced to a price equal to or lower than the lowest bid or offer price for foreign aluminum, glass or steel products plus the applicable preference. If the reduced bid or offer prices are made in writing and supersede the prior bid or offer prices, all bids or offers, including the reduced bid or offer prices, will be reevaluated in accordance with this rule.

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.

Elias Paraschos, Bid Analyst

(Name, Title)

(Printed Name and Title)

3650 Westwind Blvd, Santa Rosa, CA 95403

(Address)

PH: 800-255-2159 FAX:707-676-1878

(Phone Number) / (Fax Number)

eparaschos@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, Inc.

(Company)

(Authorized Signature) (Representative Name, Title)

Barry Chapman, Chief Financial Officer

(Printed Name and Title of Authorized Representative)

09-15-2016

(Date)

PH: 800-255-2159 FAX:707-676-1878

(Phone Number) (Fax Number)

ADDENDUM ACKNOWLEDGEMENT FORM
SOLICITATION NO.: CRFQ COR1700000001

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, Inc.

Company

Authorized Signature

10-17-2016

Date

NOTE: This addendum acknowledgement should be submitted with the bid to expedite document processing.

REQUEST FOR QUOTATION
CRFQ COR1700000001
COR238214 Drug Test Kits and Supplies

SPECIFICATIONS

1. **PURPOSE AND SCOPE:** The West Virginia Purchasing Division is soliciting bids on behalf of the Division of Corrections to establish a contract for I Cup Panel Drug Test kits (including standard and customizable), mouth swabs, other supplies and Confirmation Laboratory Services as specified in this RFQ.

   Agency has over 5,000 inmates housed in multiple correctional sites throughout the State of West Virginia. The Agency has more than 2,500 parolee offenders located throughout the state.

   In addition to drug testing of WVDOC inmates and parolee offenders, the specified drug testing kits and confirmation laboratory services may be utilized for civilian pre-employment drug testing as well as "for cause" testing on employees of the Agency.

   Drug testing kits and associated supplies shall be shipped to the facilities listed on Attachment A. In addition, Vendor agrees to provide drug testing kits and associated supplies to all new facilities added by the Agency during the term of this agreement at the same contract price.

2. **DEFINITIONS:** The terms listed below shall have the meanings assigned to them below. Additional definitions can be found in section 2 of the General Terms and Conditions.

   2.1 **"Contract Item"** or **"Contract Items"** means the list of items identified in Section 3.1 below and on the Pricing Pages.

   2.2 **"Contract Services"** means Laboratory confirmation testing as more fully described in these specifications.

   2.3

   2.4 **"Pricing Pages"** means the schedule of prices, estimated order quantity, and totals contained in wvOASIS or attached hereto as Exhibit A, and used to evaluate the Solicitation responses.

   2.5 **"Solicitation"** means the official notice of an opportunity to supply the State with goods or services that is published by the Purchasing Division.

   2.6 **"ALL INCLUSIVE"** means self-contained to prevent exposure to contamination.

   2.7 **"RFQ"** means the official request for quotation published by the Purchasing Division and identified as COR238214.

2.8 **"STATEWIDE"** means that the vendor must provide services and commodities to all DOC facilities in the state in 55 counties.

The following acronyms will correspond with the type of drug being specified going further in this RFQ:

AMP – Amphetamines
BAR – Barbiturates
BUP - Buprenorphine
BZO – Benzodiazepines
COC – Cocaine
MAMP – Methamphetamines
MDMA - Ecstasy
MTD – Methadone
OPI – Opiates
OXY – Oxycodone
PCP – Phencyclidine
PPX – Propoxyphene
SynCANN – Synthetic Cannabinoids
TCA – Tricyclic antidepressants
THC – Tetrahydrocannabinol/Marijuana

2.9 **"FDA 510 K"** refers to the notification to FDA of vendors intent to market a medical device.

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 county correctional facility. Inmate population must be a minimum of 5,000 inmates to qualify for consideration.

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.

3.3 For laboratory services, Vendor shall provide curriculum vitae of Laboratory Director with bid.

3.4 For laboratory services, Vendor shall be certified by the Substance Abuse & Mental Health Services Administration (SAMSHA) and the US Department of Health and Human Services (HHS) for employment and parole revocations for drug testing confirmations; Clinical Laboratory Improvement Amendments (CLIA) for inmate drug testing confirmations.

Vendor shall provide proof of such certifications with its bid.

4. GENERAL REQUIREMENTS:

4.1 Contract Items and Mandatory Requirements: Vendor shall provide Agency with the Contract Items listed below on an open-end and continuing basis. Contract Items must meet or exceed the mandatory requirements as shown below.

4.1.1 Inmate and Parolee drug testing kits

4.1.1.1 All Inclusive On Site Urine Screening Device- I Cup Instant Drug Test Kit 6 panel or equivalent

4.1.1.1.1 The Product shall be a 6 panel test including AMP, BARB, COC, MAMP, OPI, and THC.

4.1.1.1.2 The product shall render accurate results (rate of 97% or higher) in under a minute.

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

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

4.1.1.1.5 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

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

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

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

4.1.1.1.9 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.

4.1.1.1.10 The Product shall have a minimum 18 month shelf life.

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

4.1.1.1.12 The product shall be FDA approved for commercial distribution with an active 510K notification document.

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

4.1.1.1.13.1 Shipping Bag

4.1.1.1.13.2 Shipping container that will hold a minimum of two (2) specimen cups

4.1.1.1.13.3 Chain of custody form

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

4.1.1.2 All Inclusive On Site Urine Screening Device- I Cup Instant Drug Test Kit 10 panel or equivalent (2292)

4.1.1.2.1 The Product shall be a 10 panel test including AMP, BAR, BZO, COC, MAMP, MTD, OPI, TCA, and THC.

4.1.1.2.2 The product shall render accurate results (rate of 97% or higher) in under a minute.

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

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

4.1.1.2.5 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

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

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

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

4.1.1.2.9 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.

4.1.1.2.10 The Product shall have a minimum 18 month shelf life.

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

4.1.1.2.12 The product shall be FDA approved for commercial distribution with an active 510K notification document.

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

4.1.1.2.13.1 Shipping Bag

4.1.1.2.13.2 Shipping container that will hold a minimum of two (2) specimen cups

4.1.1.2.13.3 Chain of custody form

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

4.1.1.3 Customizable All Inclusive On Site Urine Screening Device- I Cup Instant Drug Test Kit 13 panel or equivalent

4.1.1.3.1 The Product shall be a 13 panel test including (at a minimum) AMP, BAR, BZO, COC, MAMP, MTD, OPI, TCA, and THC, and shall also be customizable at any time at no additional cost.

4.1.1.3.2	The product shall render accurate results (rate of 97% or higher) in under a minute.
4.1.1.3.3	The product shall have built in adulteration detection to aid in the prevention of sample tampering.
4.1.1.3.4	The product shall be all inclusive without a separate testing device.
4.1.1.3.5	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
4.1.1.3.6	The product shall be able to detect drugs indicated on the panel simultaneously.
4.1.1.3.7	The product shall not leak during air/ground shipping.
4.1.1.3.8	The cup shall have a minimum fill line clearly displayed on the outside of the cup.
4.1.1.3.9	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.
4.1.1.3.10	The Product shall have a minimum 18 month shelf life.
4.1.1.3.11	The product shall include Clinical Laboratory Improvement Amendments (CLIA) cut off levels, and shall have the ability to be confirmed via laboratory confirmation testing.
4.1.1.3.12	The product shall be FDA approved for commercial distribution with an active 510K notification document.
4.1.1.3.13	Vendor shall provide, at their expense, the following samples upon request:
4.1.1.3.13.1	Shipping Bag
4.1.1.3.13.2	Shipping container that will hold a minimum of two (2) specimen cups

4.1.1.3.13.3 Chain of custody form

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

4.1.1.4 Panel Saliva Test for oral fluids 6 panel

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

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

4.1.1.4.3 The product shall render accurate results (rate of 97% or higher) in under a minute.

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

4.1.1.4.5 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

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

4.1.1.4.7 The Product shall have a minimum 18 month shelf life.

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

4.1.1.4.9 The product shall be FDA approved for commercial distribution with an active 510K notification document.

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

4.1.1.4.10.1 Shipping Bag

4.1.1.4.10.2 Shipping container that will hold a minimum of two (2) specimen cups

4.1.1.4.10.3 Chain of custody form

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

4.1.1.4.12 The product shall have fast turn-around time from receipt of specimen (48 hours 2 negative, 72 hours positive).

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

4.2 Employment/Employee drug testing kits

4.2.1 All Inclusive On Site Urine Screening Device- I Cup Instant Drug Test Kit 6 panel or equivalent

4.2.1.1 The Product shall be a 6 panel test including AMP, BARB, COC, MAMP, OPI, and THC.

4.2.1.2 The product shall render accurate results (rate of 97% or higher) in under a minute.

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

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

4.2.1.5 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

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

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

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

4.2.1.9 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.

4.2.1.10 The Product shall have a minimum 18 month shelf life.

4.2.1.11 The product shall include Substance Abuse & Mental Health Services Administration (SAMSHA) and the US Department of Health and Human Services (HHS) cut off levels, and shall have the ability to be confirmed via laboratory confirmation testing.

4.2.1.12 The product shall be FDA approved for commercial distribution with an active 510K notification document.

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

4.2.1.13.1 Shipping Bag

4.2.1.13.2 Shipping container that will hold a minimum of two (2) specimen cups

4.2.1.13.3 Chain of custody form

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

4.2.2 All Inclusive On Site Urine Screening Device- I Cup Instant Drug Test Kit 10 panel or equivalent (2292)

4.2.2.1 The Product shall be a 10 panel test including AMP, BAR, BZO, COC, MAMP, MTD, OPI, TCA, and THC.

4.2.2.2 The product shall render accurate results (rate of 97% or higher) in under a minute.

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

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

4.2.2.5 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

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

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

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

4.2.2.9 The state 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.

4.2.2.10 The Product shall have a minimum 18 month shelf life.

4.2.2.11 The product shall include Substance Abuse & Mental Health Services Administration (SAMSHA) and the US Department of Health and Human Services (HHS) cut off levels, and shall have the ability to be confirmed via laboratory confirmation testing..

4.2.2.12 The product shall be FDA approved for commercial distribution with an active 510K notification document.

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

4.2.2.13.1 Shipping Bag

4.2.2.13.2 Shipping container that will hold a minimum of two (2) specimen cups

4.2.2.13.3 Chain of custody form

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

4.2.3 Customizable All Inclusive On Site Urine Screening Device- 1 Cup Instant Drug Test Kit 13 panel or equivalent

4.2.3.1 The Product shall be a 13 panel test including (at a minimum) AMP, BAR, BZO, COC, MAMP, MTD, OPI, TCA, and THC, and shall also be

customizable at any time at no additional cost.

4.2.3.2 The product shall render accurate results (rate of 97% or higher) in under a minute.

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

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

4.2.3.5 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

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

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

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

4.2.3.9 The state 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.

4.2.3.10 The Product shall have a minimum 18 month shelf life.

4.2.3.11 The product shall include Substance Abuse & Mental Health Services Administration (SAMSHA) and the US Department of Health and Human Services (HHS) cut off levels, and shall have the ability to be confirmed via laboratory confirmation testing.

4.2.3.12 The product shall be FDA approved for commercial distribution with an active 510K notification document.

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

4.2.3.13.1 Shipping Bag

4.2.3.13.2 Shipping container that will hold a minimum of two (2) specimen cups

4.2.3.13.3 Chain of custody form

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

4.2.4 Panel Saliva Test for oral fluids 6 panel

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

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

4.2.4.3 The product shall render accurate results (rate of 97% or higher) in under a minute.

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

4.2.4.5 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

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

4.2.4.7 The Product shall have a minimum 18 month shelf life.

4.2.4.8 The product shall include Substance Abuse & Mental Health Services Administration (SAMSHA) and the US Department of Health and Human Services (HHS) cut off levels, and shall have the ability to be confirmed via laboratory confirmation testing.

4.2.4.9 The product shall be FDA approved for commercial distribution with an active 510K notification document.

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

4.2.4.10.1 Shipping Bag

4.2.4.10.2 Shipping container that will hold a minimum of two (2) specimen cups

4.2.4.11 Chain of custody form

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

4.2.4.13 The product shall have fast turn-around time from receipt of specimen (48 hours 2 negative, 72 hours positive).

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

4.3 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 changes 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.

4.4 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.

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

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

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

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

4.5.4 Drug testing kit shall not require refrigeration.

4.5.5 Drug testing kit must utilize colloidal gold technology.

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

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

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

4.5.9 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.

4.5.10 The label shall provide a place to enter collection time, date, and client initials.

4.5.11 Packaging

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

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

4.5.11.3 The name and location of each Division of Corrections facility is listed in Exhibit A. The Vendor shall provide the contract items, at contract price, to any additional DOC facility(s) that may open, or require equipment and supplies during the course of the contract.

4.5.12 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

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

4.5.14 The confirmation laboratory shall be currently certified and maintain certification by the US Department of Health and Human Services (HHS) for all confirmations; Clinical Laboratory Improvement Amendments (CLIA) for inmate confirmations, and Substance Abuse Mental Health Administration (SAMSHA), to meet the standards for federal workplace drug testing programs for employment and parolee offender

revocations. A copy of the certification should be provided with the bid.

4.5.15 The confirmation laboratory may, for inmate testing, be performed by certified Clinical Laboratory Improvement Amendments (CLIA) licensed laboratories; however, the Agency retains the requirement for SAMSHA lab testing for employee and pre-employment screenings. In addition, Agency will utilize SAMSHA lab testing for all parole revocations.

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

4.5.17 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).

Inmates and Parolee Offenders: The purpose of this testing is for criminal justice purposes and the Agency does not use administrative cutoffs for workplace testing. As such, the Agency requires that the confirmation lab test to limit of detection (LOD), which are 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 therefrom for both institutional discipline and probation revocation proceeding.

Civilian Pre-employment and Staff "For Cause" Drug Testing: The confirmation testing for this category shall be conducted in compliance with the Guidelines for Federal Workplace Drug Testing Programs. These Guidelines can be located at: https://www.federalregister.gov/articles/2016/06/30/2016-15469/mandatory-guidelines-for-federal-workplace-drug-testing-programs

4.5.18 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.

4.5.19 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.

4.5.20 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.

4.5.21 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.

4.6 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.

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

5. CONTRACT AWARD:

5.1 **Contract Award:** The Contract is intended to provide Agencies with a purchase price on all Contract Items. The Contract shall be awarded to the Vendor that provides the Contract Items meeting the required specifications for the lowest overall total cost as shown on the Pricing Pages.

5.2 **Pricing Pages:** Vendor should complete the Pricing Pages by indicating unit price, and extended price. Vendor should complete the Pricing Pages in their entirety as failure to do so may result in Vendor's bids being disqualified.

5.2.1 The Pricing Pages contain a list of the Contract Items and estimated purchase volume. The estimated purchase volume for each item represents the approximate volume of anticipated purchases only. No future use of the Contract or any individual item is guaranteed or implied.

5.2.2 Vendor should electronically enter the information into the Pricing Pages through wvOASIS, if available, or as an electronic document. In most cases, the Vendor can request an electronic copy of the Pricing Pages for bid purposes by sending an email request to the following address: Crystal.G.Rink@wv.gov.

6. **PERFORMANCE:** Vendor and Agency shall agree upon a schedule for performance of contract Services and Contract Services Deliverables, unless such a schedule is already included herein by Agency. In the event that this Contract is designated as an open-end contract, Vendor shall perform in accordance with the release orders that may be issued against this Contract.

7. **ORDERING AND PAYMENT:**

   7.1 **Ordering:** Vendor shall accept orders through wvOASIS, regular mail, facsimile, e-mail, or any other written form of communication. Vendor may, but is not required to, accept on-line orders through a secure internet ordering portal/website. If Vendor has the ability to accept on-line orders, it should include in its response a brief description of how Agencies may utilize the on-line ordering system. Vendor shall ensure that its on-line ordering system is properly secured prior to processing Agency orders on-line.

   7.2 **Payment:** Agency shall pay flat fee for confirmation services, and as shown on the Pricing Pages, for all Contract Services performed and accepted under this Contract. Vendor shall accept payment in accordance with the payment procedures of the State of West Virginia.

8. **TRAVEL:** Vendor shall be responsible for all mileage and travel costs, including travel time, associated with performance of this Contract. Any anticipated mileage or travel costs may be included in the flat fee or hourly rate listed on Vendor's bid, but such costs will not be paid by the Agency separately.

9. **FACILITIES ACCESS:** Performance of Contract Services may require access cards and/or keys to gain entrance to Agency's facilities. In the event that access cards and/or keys are required:

   9.1 Vendor must identify principal service personnel which will be issued access cards and/or keys to perform service.

   9.2 Vendor will be responsible for controlling cards and keys and will pay replacement fee, if the cards or keys become lost or stolen.

   9.3 Vendor shall notify Agency immediately of any lost, stolen, or missing card or key.

   9.4 Anyone performing under this Contract will be subject to Agency's security protocol and procedures.

9.5 Vendor shall inform all staff of Agency's security protocol and procedures

10. DELIVERY AND RETURN:

10.1 **Delivery Time:** Vendor shall deliver standard orders within five (5) working days after orders are received. Vendor shall deliver emergency orders within two (2) working day(s) after orders are received. Vendor shall ship all orders in accordance with the above schedule and shall not hold orders until a minimum delivery quantity is met.

10.2 **Late Delivery:** The Agency placing the order under this Contract must be notified in writing if orders will be delayed for any reason. Any delay in delivery that could cause harm to an Agency will be grounds for cancellation of the delayed order, and/or obtaining the items ordered from a third party.

Any Agency seeking to obtain items from a third party under this provision must first obtain approval of the Purchasing Division.

10.3 **Delivery Payment/Risk of Loss:** Standard order delivery shall be F.O.B. destination to the Agency's location. Vendor shall include the cost of standard order delivery charges in its bid pricing/discount and is not permitted to charge the Agency separately for such delivery. The Agency will pay delivery charges on all emergency orders provided that Vendor invoices those delivery costs as a separate charge with the original freight bill attached to the invoice.

10.4 **Return of Unacceptable Items:** If the Agency deems the Contract Items to be unacceptable, the Contract Items shall be returned to Vendor at Vendor's expense and with no restocking charge. Vendor shall either make arrangements for the return within five (5) days of being notified that items are unacceptable, or permit the Agency to arrange for the return and reimburse Agency for delivery expenses. If the original packaging cannot be utilized for the return, Vendor will supply the Agency with appropriate return packaging upon request. All returns of unacceptable items shall be F.O.B. the Agency's location. The returned product shall either be replaced, or the Agency shall receive a full credit or refund for the purchase price, at the Agency's discretion.

10.5 **Return Due to Agency Error:** Items ordered in error by the Agency will be returned for credit within 30 days of receipt, F.O.B. Vendor's location. Vendor shall not charge a restocking fee if returned products are in a resalable condition. Items shall be deemed to be in a resalable condition if they are unused and in the original packaging. Any restocking fee for items not in a resalable condition shall be the lower of the Vendor's customary restocking fee or 5% of the total invoiced value of the returned items.

11. VENDOR DEFAULT:

11.1 The following shall be considered a vendor default under this Contract.

11.1.1 Failure to provide Contract Items in accordance with the requirements contained herein.

11.1.2 Failure to comply with other specifications and requirements contained herein.

11.1.3 Failure to comply with any laws, rules, and ordinances applicable to the Contract Services provided under this Contract.

11.1.4 Failure to remedy deficient performance upon request.

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: Kristin Champion
Telephone Number: 800-255-2159
Fax Number: 707-676-9220
Email Address: kchampion@redwoodtoxicology.com

Attachment A
COR238214 Drug Test Kits

Facilities

Anthony Correctional
313 Anthony Center Drive
White Sulphur Springs, WV 24986

Beckley Correctional
111 S. Eisenhower Drive
Beckley, WV 25801

Charleston Correctional
1356 Hansford Street
Charleston, WV 25301

Denmar Correctional
4319 Denmar Road
Hillsboro, WV 24946

Huntington Work Release
1236 Fifth Avenue
Huntington, WV 25701

Huttonsville Correctional
PO Box 1
Huttonsville, WV 26273

Lakin Correctional
11264 Ohio River Road
West Columbia, WV 25287

Martinsburg Correctional
38 Grapevine Road
Martinsburg, WV 25401

Mt. Olive Correctional
1 Mountainside Way
Mt. Olive, WV 25185

Northern Correctional
112 Northern Regional Correctional Dr.
Moundsville, WV 26041

Ohio County Correctional
1501 Eoff Street
Wheeling, WV 26003

Parkersburg Correctional
225 Holiday Hills Drive
Parkersburg, WV 26104

Pruntytown Correctional
PO Box 159
Grafton, WV 26354

St. Marys Correctional
2880 N. Pleasants Highway
St. Marys, WV 26170

Salem Correctional
7 Industrial Blvd.
Salem, WV 26426

Parole Offices

Beckley Parole Office
3225 Robert C. Byrd Drive
Beckley, WV 25801

Charleston Parole Office
1339 Plaza East
Charleston, WV 25301

Clarksburg Parole Office
215 West Main Street
Clarksburg, WV 26301

Elkins Parole Office
1513 Harrison Avenue, Unit 27
Elkins, WV 26241

Huntington Parole Office
801 Madison Avenue
Huntington, WV 25704

Keyser Parole Office
102 North Main Street
Keyser, WV 26726

Lewisburg Parole Office
913 Washington St. W Ste 1
Lewisburg, WV 24901

Logan Parole Office
229 Stratton Street, Rm 306
Logan, WV 25601

Martinsburg Parole Office
1520 Winchester Avenue
Martinsburg, WV 25405

Parkersburg Parole Office
225 Holiday Hills Drive, Ste 1
Parkersburg, WV 26104

Princeton Parole Office
159 Davis Street
Princeton, WV 24739

Ripley Parole Office
117 North Court Street
Ripley, WV 25271

Welch Parole Office
110 Park Avenue Suite 111
Welch, WV 24801

Wheeling Parole Office
1025 Main Street
Wheeling, WV 26003

Administrative

Central Office
1409 Greenbrier Street
Charleston, WV 25311

WV Corrections Academy
PO Box 850
Glenville, WV 26351

Moundsville Training Center
818 Jefferson Avenue
Moundsville, WV 26041

Exhibit A	CRFQ COR1700000001

COR238214 - Drug Testing Kits & Confirmation Services

Item No.	Description	Estimated Quantity	Unit Price	Extended Price
1	6-Panel Urine Test Kit (Inmate/Parolee)	2000	$2.29	$4,580.00
2	10-Panel Urine Test Kit (Inmate/Parolee)	30000	$2.34	$70,200.00
3	13-Panel Urine Test Kit (Inmate/Parolee)	13000	$3.89	$50,570.00
4	Oral Swab Test Kit (Inmate/Parolee)	5000	$ 5.40	$27,000.00
5	6-Panel Urine Test Kit (Employee)	100	$2.29	$229.00
6	10-Panel Urine Test Kit (Employee)	100	$2.34	$234.00
7	13-Panel Urine Test Kit (Employee)	100	$3.89	$389.00
8	Oral Swab Test Kit (Employee)	100	$5.40	$540.00
9	Laboratory confirmation (Inmate/Parolee)	100	$ 9.50/drug*	$950.00
10	Laboratory confirmation (Employee)	100	$13.00**	$1,300.00
11	MRO, or Lab Representative, as Expert Witness	100	$300/hour***	$ 30,000.00
12	Training	1	$0.00	$0.00
13	Emergency Delivery Order	1	$ 50.00	$ 50.00
14	Shipping Charge (less than 5 specimens per delivery)	1	$25.00	$25.00
15	EtG and EtS testing	1000	$ 12.00****	$12,000.00****
			Total Bid Amount	$ 198,067.00

Bidder/Vendor Information

Name	Redwood Toxicology Laboratory, Inc.
Address	3650 Westwind Blvd, Santa Rosa, CA 95403
Phone Number	800-255-2159
Fax Number	707-676-1878
Email	bids@redwoodtoxicology.com
Authorized Signature	

Actual Quantities ordered may be more or less than noted on bid form Exhibit A

**Price only applies for specimens in RTL- or Alere affiliate-provided supply or device.*

***Employee Testing to be performed at Alere Toxicology. Includes DOT Panel - Screen + Automatic Confirmation.*

****Expert Witness Testimony : Toxicologist - $300/hour including travel with a per day maximum of $1000.00. MRO services not provided.*

*****EtG Testing Options - choose during account set-up:*
EtG Dip device @ $2.85
EtG Laboratory Screen Only (049 or 050) @ $5.00
EtG/EtS Confirmation Only @ $9.50
EtG Combo Test (Screen + Confirmation) (647) @ $12.00

REDWOOD TOXICOLOGY LABORATORY

Confidence in testing.

Additional Optional Pricing Schedule
West Virginia DOC
CRFQ 0608_COR1700000001 - Drug Test Kits for Inmates, Parolees, and Employees

Items highlighted in green match line items specifically requested in the bid.

Section I: Rapid Drug & Alcohol Screening Devices - Urine

iCUP A.D. SUBSTANCE ABUSE TEST DEVICE – with adulteration

PART NUMBER	DRUG(S)	CONFIGURATION	PRICE PER DEVICE	BOX PRICE (25/BOX)
01 102 2022	6	iCup A.D. 6 AMP1000/BZO/COC300/MAMP1000/OPI2000/THC w/adulteration (OX, SG, PH)	$2.29	$57.25
01 102 2023	6	iCup A.D. 6 AMP1000/COC/MAMP1000/OPI2000/PCP/THC w/adulteration (OX, SG, PH)	$2.29	$57.25
01 102 2037	6	iCup A.D. 06 AMP300/COC300/MDMA/OPI2000/OXY/THC w/adulteration (OX, SG, PH)	$2.29	$57.25
01 102 2038	8	iCup A.D. 08 AMP1000/BAR/BZO/COC300/MAMP1000/OPI2000/PCP/THC w/adulteration (OX, SG, PH)	$2.29	$57.25
01 102 2069	8	iCup A.D. 08 AMP1000/BZO/COC300/MAMP1000/MOP300/OXY/PCP/THC w/adulteration (OX,CR,PH)	$2.29	$57.25
01 102 2074	10	iCup A.D. 10 AMP1000/BAR/BZO/COC300/MAMP1000/MTD/OPI2000/OXY/ PPX/THC w/adulteration (OX, CR, PH)	$2.34	$58.50
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)	$2.34	$58.50
01 102 2027	12	iCup A.D. AMP1000/BAR/BZO/COC300/MAMP1000/MTD/OPI2000/OXY/PCP/PPX/ TCA/THC w/adulteration (OX, SG, PH)	$3.89	$97.25

iCUP A.D. SUBSTANCE ABUSE TEST DEVICE – without adulteration

PART NUMBER	DRUG(S)	CONFIGURATION	PRICE PER DEVICE	BOX PRICE (25/BOX)
01 102 2028	13	iCup 13 AMP1000/BAR/BUP/BZO/COC300/MAMP/MTD/OPI2000/OXY/PCP/PPX/ TCA/THC	$3.89	$97.25

iCUP DX SUBSTANCE ABUSE TEST DEVICE – with adulteration

PART NUMBER	DRUG(S)	CONFIGURATION	PRICE PER DEVICE	BOX PRICE (25/BOX)
01 577 0202	14	iCUP DX 14 AMP500/BAR300/BZO300/BUP10/COC150/MDMA500/MAMP500/MTD300 MOP300/OXY100/PCP25/PPX300/TCA1000/THC50 (CR,NI,PH,SG,BI) - *CLIA Waived*	$3.89	$97.25

PANEL-DIP SUBSTANCE ABUSE TEST DEVICE

PART NUMBER	DRUG(S)	CONFIGURATION	PRICE PER DEVICE	BOX PRICE (25/BOX)
01 501 0008	1	Single Urine Dip for ETG - *For Forensic Use Only*	$2.85	$71.25
01 191 6335	1	PANEL DIP 01 K2 SPICE 30 - *For Forensic Use Only*	$2.00	$50.00

Section II: Rapid Drug & Alcohol Testing Services - Oral Fluids

ORAL FLUID DRUGS OF ABUSE - *For Forensic Use Only*

PART NUMBER	DRUG(S)	CONFIGURATION	PRICE PER DEVICE	BOX PRICE (25/BOX)
01 102 2025	6	iScreen Oral Fluid Device AMP50/COC20/MAMP50/OPI40/PCP10/THC12 - *FFUO*	$3.85	$96.25
01 102 2083	6	OrAlert 6 Oral Fluid Device AMP50/BZO10/COC20/MAMP50/OPI40/THC100 - *FFUO*	$5.00	$125.00
01 577 0106	11	Uscreen Oral Fluid 11 ALCO.02/THC50/COC20/OPI40/AMP50/MAMP50/BAR50 /BZO10/BUP 5/MTD30/ OXY20 - FFUO	$5.40	$135.00

ADDITIONAL DRUGS OF ABUSE TEST DEVICES

Redwood Toxicology's complete rapid test device catalogue may be provided to the State upon request. We are happy to negotiate the addition of products and services depending on the State's needs throughout the term of the contract.

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.

REDWOOD TOXICOLOGY LABORATORY

Confidence in testing.

Additional Optional Pricing Schedule
West Virginia DOC
CRFQ 0608_COR1700000001 - Drug Test Kits for Inmates, Parolees, and Employees

Items highlighted in green match line items specifically requested in the bid.

Section III: Laboratory Drug & Alcohol Testing Services - Urine

LABORATORY URINALYSIS (Redwood) - Inmate & Parolee

TEST CODE	DRUG(S)	CONFIGURATION	PRICE PER SPECIMEN
Various	1	GC-MS, LC-MS/MS or GC-FID Standard Urine Confirmation* - cost per drug	$ 9.50
049/050	1	Ethyl Glucuronide (EtG) Alcohol Metabolite - Stand-Alone Screen Only	$ 5.00
647	1	Ethyl Glucuronide/Ethyl Sulfate (EtG/EtS) Alcohol metabolite - EtG Screen with Automatic Confirmation of Positives for both EtG & EtS	$ 12.50
6473	19	Synthetic Marijuana (K2/Spice) - Standard Panel	$ 18.00
8474	30	Synthetic Marijuana (K2/Spice) - Premium Panel	$ 45.00

**Laboratory confirmations only available on devices obtainable through an Alere subsidiary; RTL will not provide confirmations on non-Alere devices.*

LABORATORY URINALYSIS (Alere Toxicology) - Employment (DOT)

TEST CODE	DRUG(S)	CONFIGURATION	PRICE PER SPECIMEN
Various	1	DOT Employee Panel: Screen and Automatic Confirmation *Heroin metabolite (6-MAM), Amphetamine/Methamphetamine, Cocaine, MDMA (Ecstasy), Opiates, PCP, THC*	$ 13.00

Section IV: Laboratory Drug & Alcohol Testing Services - Oral Fluid

LABORATORY URINALYSIS (Redwood) - Inmate & Parolee

TEST CODE	DRUG(S)	CONFIGURATION	PRICE PER SPECIMEN
2101001	N/A	Quantisal Oral Fluid Collection Device - ***purchase required prior to testing*** *This collection device must be utilized to confirm results from UScreen Oral Fluid Device. However, iScreen OFD and OrAlert devices may be sent directly to the lab without use of a Quantisal Oral Fluid Collection Device.*	$ 2.00
Various	1	GC-MS, LC-MS/MS or GC-FID Standard Oral Fluid Confirmation - cost per drug	$ 9.50

**Laboratory confirmations only available on specimens in Quantisal oral fluid collection devices or on other rapid test devices obtainable through an Alere subsidiary; RTL will not provide confirmations on non-Alere devices.*

ADDITIONAL LABORATORY TESTS

Redwood Toxicology's complete laboratory test menu may be provided to the State upon request. We are happy to negotiate the addition of products and services depending on the State's needs throughout the term of the contract.

REDWOOD TOXICOLOGY LABORATORY

Confidence in testing.

Additional Optional Pricing Schedule
West Virginia DOC
CRFQ 0608_COR1700000001 - Drug Test Kits for Inmates, Parolees, and Employees

Items highlighted in green match line items specifically requested in the bid.

Section V: Supplemental Services

TEST CODE	DESCRIPTION	OCCURRENCE
CORT	In-Person Court Testimony (Toxicologist)	$300 per hour / $1000 max per day
	Training	$ -
	Emergency Delivery - Within 2 business days of reciept	$ 50.00
FEDEX	Short Shipment - Less than Five (5) Specimens	$ 25.00
AFFD	Affidavits	$ 100.00
INTP	Interpretations	$ 100.00
	Telephonic or Webinar Court Testimony	$ 250.00

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 when 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. Fewer than five (5) specimens sent to the lab by next day air service will be assessed a twenty-five dollar ($25.00) charge per shipment.

Rev. 04/14

State of West Virginia

NOT APPLICABLE

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:**

____ 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,**

____ 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,**

____ 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:**

____ 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:**

____ 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:**

____ 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:**

____ 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:**

____ 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*.**

____ 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:_____ **Signed:**_____

Date:_____ **Title:**_____

RFQ No. CRFQ COR1700000001

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, Inc.

Authorized Signature: _____ Date: 10-03-2016

~~State of~~ _____

County of _____, to-wit: see attached certificate

Taken, subscribed, and sworn to before me this ___ day of _____, 20___.

My Commission expires _____, 20___.

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 3rd (Date) day of October (Month), 2016 (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 _____
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: 10/3/16

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

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REDWOOD TOXICOLOGY LABORATORY

Confidence in testing.

Response to Qualifications

To ensure that we have met all requirements for the proposed products and services, what follows are the specifications as taken directly from the RFP. The specifications from the RFP are in **black**; RTL's responses to each requirement are written in green.

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 county correctional facility. Inmate population must be a minimum of 5,000 inmates to qualify for consideration.

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 agencies with the highest quality drug testing 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 dozens of state and county level departments of corrections, mental and behavioral health departments, children and family services agencies, rehabilitation facilities, probation/parole agencies and drug courts. In fact, we are the incumbent provider of devices and laboratory services to the West Virginia Division of Corrections. Many of our corrections clients have inmate populations of 5,000 or more. 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 any drug testing program a success.

Please note that RTL will be using our sister laboratory under Alere, Inc.—Alere Toxicology—to provide DOT employee testing, including confirmation testing on employee tests. Alere Toxicology provides comprehensive services and products to employers looking to implement or enhance their drug and alcohol testing programs. Having specialized in workplace testing for over 30 years, Alere Toxicology understands the requirements of these unique programs and the state and federal laws that regulate them. Hundreds of government agencies use Alere Toxicology for employee testing, including the Federal Department of Transportation in Washington and the Commonwealth of Virginia's Department of Corrections, among others.

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 provided RTL profession reference sheet submitted with our bid.

3.3 For laboratory services, Vendor shall provide curriculum vitae of Laboratory Director with bid.

Please find the Curriculum Vitae for RTL's Laboratory Scientific Director, Suman Rana; RTL's Chief Toxicologist, Wayne Ross; and Alere Toxicology's Laboratory Director, David Green, submitted with our bid response.

3.4 For laboratory services, Vendor shall be certified by the Substance Abuse & Mental Health Services Administration (SAMSHA) and the US Department of Health and Human Services (HHS) for employment and parole revocations for drug testing confirmations; Clinical Laboratory Improvement Amendments (CLIA) for inmate drug testing confirmations.

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
- Drug Enforcement Agency (DEA)

RTL will perform inmate drug testing confirmations through our CLIA laboratory.

Alere Toxicology is also certified by SAMHSA, registered with the DEA, and has accreditation from CAP/FUDT.

REDWOOD TOXICOLOGY LABORATORY

Confidence in testing.

Response to Technical Specifications

To ensure that we have met all requirements for the proposed products and services, what follows are the specifications as taken directly from the RFP. The specifications from the RFP are in **black**; RTL's responses to each requirement are written in green.

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4. GENERAL REQUIREMENTS:
4.1 Contract Items and Mandatory Requirements: Vendor shall provide Agency with the Contract Items listed below on an open-end and continuing basis. Contract Items must meet or exceed the mandatory requirements as shown below.

4.1.1 Inmate and Parolee drug testing kits

4.1.1.1 All Inclusive On Site Urine Screening Device - I Cup Instant Drug Test Kit 6 panel or equivalent

4.1.1.1.1 The Product shall be a 6 panel test including AMP, BARB, COC, MAMP, OPI, and THC.

RTL will provide the State with an 8 panel **Alere iCup® A.D. Drug Screen** device to meet the drug configuration requested above. The specific iCup A.D. we are offering, RTL part number 011022038, includes the following configuration: AMP1000 / BAR300 / BZO300 / COC300 / mAMP1000 / OPI2000 / PCP25 / THC50 + S.V.T. OX, SG, PH. This device covers the drugs requested in addition to testing for PCP and Benzodiazepines, which we have included at no additional charge.

4.1.1.1.2 The product shall render accurate results (rate of 97% or higher) in under a minute.

Device accuracy varies based on drug configuration, with accuracy being specific to each drug strip. In accordance with what was stated in A46 of Amendment 4, the State is interested in overall product accuracy, which is to be taken as an average. The iCup device being offered by RTL for the 6-drug line item described above has an average accuracy rate of 95.6%. Please see the package insert we have provided with this bid response for more detailed accuracy information by drug.

In accordance with what was stated in A36 of Amendment 4, the state will accept results that are available within 5 minutes. The iCup device being offered will produce results in 5 minutes or less.

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

The iCup A.D. device comes with built-in adulteration detection strips. Specimen validity combinations include Creatinine (CR), Glutaraldehyde (GL), Nitrites (NI), Oxidants (OX), pH, and Specific Gravity (SG). Please see our Product List for available configurations.

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

Each of RTL's urinalysis cups is all-inclusive and self-contained. No other supplies or chemicals are need to perform testing. RTL drug testing kits do not require electricity, special plumbing, instrumentation, calibration, a laboratory environment or refrigeration in order to be used. Testing kits are completely portable and are ready for immediate use in any location.

4.1.1.1.5 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.

RTL's drugs of abuse screening devices are easy to read to aid in correct interpretation of results. If two red 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 sufficient specimen volume, adequate membrane wicking, and correct procedural technique, a control line is included on each screening device. Please see the provided product inserts for more specific information on proper usage and reading of results for each specific test device.

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

The rapid test device provided by RTL can detect multiple drugs simultaneously. Devices are available in various configurations of drugs including Amphetamines (AMP), Methamphetamines (MAMP), Barbiturates (BAR), Benzodiazepines (BZO), Buprenorphine (BUP), Cocaine (COC), Ecstasy (MDMA), Methadone (MTD), Opiates (OPI), Oxycodone (OXY), PCP, Propoxyphene (PPX), Tri-Cyclic Antidepressants (TCA), and Marijuana (THC). Specimen validity combinations include Creatinine (CR), Gluteraldehyde (GL), Nitrites (NI), Oxidants (OX), pH, and Specific Gravity (SG).

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

The iCup devices are sealed and leak proof when the lids are screwed on according to proper protocol. Specimen may be shipped directly to the laboratory for confirmation in the device without transferring the specimen to another container.

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

The iCup devices offered are graduated but do not have a minimum fill line.

4.1.1.1.9 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.

In accordance with what was stated in A44 of Amendment 4, RTL shall provide the State with newly requested configurations, if available, with the same number of drugs at no additional charge. Should the requested configurations not be available through RTL's current catalogue and a new cup would have to be created, the State would need to work with RTL to determine feasibility of the configuration; a

volume commitment may be required, as well as an estimated 90 to 180 days of lead time, for custom cups created specifically for the State. Please note that new cups created may or may not be the same exact style or brand of cup, depending on product feasibility or availability; RTL will discuss options with the State prior to creation.

4.1.1.1.10 The Product shall have a minimum 18 month shelf-life.

In accordance with what was stated in A42 of Amendment 4, RTL will provide the State with drug testing kits with a shelf-life of a minimum of 12 months from the time of delivery. Please note that devices should never be used beyond the date of expiration, which is printed on the packaging of the product.

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

In accordance with what was stated in A43 of amendment 4, the state has removed the requirement for CLIA cut-off levels and replaced it with a requirement for the devices to be CLIA-waived. Most of RTL's devices are not categorized as CLIA-waived, as this kind of device is unnecessary for most forensic criminal justice testing needs; further, proper CLIA-waived device protocol would require additional time and measures to perform.

CLIA-waived devices are typically used for facilities with active waived laboratory licenses through CLIA. As indicated on page 4 of the document created by CMS, entitled "Clinical Laboratory Improvement Amendments: How to Obtain a CLIA Certificate of Waiver," if an agency performs waived tests, CLIA requires that they "follow the manufacturer's instructions for the waived tests you are performing," which includes performing quality control measures using positive and negative controls. Unless each State facility using these devices has a CLIA-waived license and intends to conduct quality control testing, CLIA waived products are not necessary.

Please see RTL's pricing schedule for information regarding which devices are categorized as CLIA-waived and which devices are not.

4.1.1.1.12 The product shall be FDA approved for commercial distribution with an active 510K notification document.

Included with this bid response are active 510K documents for RTL's offered urine cup devices. Oral fluid testing devices are for forensic use only and do not have active 510K documentation.

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

- Shipping Bag
- Shipping container that will hold a minimum of two (2) specimen cups
- Chain of custody form

RTL provides all the necessary urine specimen collection and shipping supplies to its clients at no additional cost. For urine testing, these supplies include:

- 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 (for sending in less than five specimens without accruing charge)

Next day air service of inbound specimens sent to RTL for testing is provided at no charge when 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. Please see the bid form for details on shipping fees.

Samples of our supplies will be provided upon request.

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

Each rapid test device is individually packaged in a sealed foil pouch with the part number, expiration date and specific drug configuration and cutoffs.

4.1.1.2 All Inclusive On Site Urine Screening Device – I Cup Instant Drug Test Kit 10 panel or equivalent (2292)

4.1.1.2.1 The Product shall be a 10 panel test including AMP, BAR, BZO, COC, MAMP, MTD, OPI, TCA, and THC.

RTL will provide the State with a 10 panel **Alere iCup® A.D. Drug Screen** device to meet the drug configuration requested above. The specific iCup A.D. we are offering, RTL part number 011022129, includes the following configuration: AMP1000 / BAR300 / BZO300 / COC300 / mAMP1000 / MTD300 / OPI2000 / PCP25 / TCA1000 / THC50 + S.V.T. OX, SG, PH, NI, GL, CR.

4.1.1.2.2 The product shall render accurate results (rate of 97% or higher) in under a minute.

Device accuracy varies based on drug configuration, with accuracy being specific to each drug strip. In accordance with what was stated in A46 of Amendment 4, the State is interested in overall product accuracy, which is to be taken as an average. The iCup device being offered by RTL for the 10-drug line item described above has an average accuracy rate of 95.4%. Please see the package insert we have provided with this bid response for more detailed accuracy information by drug.

In accordance with what was stated in A36 of Amendment 4, the state will accept results that are available within 5 minutes. The iCup device being offered will produce results in 5 minutes or less.

For sections 4.1.1.2.3 through 4.1.1.2.14, please see our responses to section 4.1.1.1. These specifications all describe the same iCup A.D. type of product offered by Redwood.

4.1.1.3 Customizable All Inclusive On Site Urine Screening Device – I Cup Instant Drug Test Kit 13 panel or equivalent

4.1.1.3.1 The Product shall be a 13 panel test including (at a minimum) AMP, BAR, BZO, COC, MAMP, MTD, OPI, TCA, and THC, and shall also be customizable at any time at no additional cost.

RTL will provide the State with an upgraded **Alere iCup® Dx 14 Drug Screen Cup** device to meet the drug configuration requested above. The specific iCup Dx we are offering, RTL part number 015770202, includes the following configuration: AMP500 / BAR300 / BZO300 / BUP10 / COC150 / MDMA500 / MAMP500 / MTD300 / MOP300 / OXY100 / PCP25 / PPX300 / TCA1000 / THC50 + **CR, NI, PH, SG, BI.** This particular iCup DX is categorized as CLIA-waived.

In accordance with what was stated in A44 of Amendment 4, RTL shall provide the State with newly requested configurations, if available, with the same number of drugs at no additional charge. Should the requested configurations not be available through RTL's current catalogue and a new cup would have to be created, the State would need to work with RTL to determine feasibility of the configuration; a volume commitment may be required, as well as an estimated 90 to 180 days of lead time, for custom cups created specifically for the State. Please note that new cups created may or may not be the same exact style or brand of cup, depending on product feasibility or availability; RTL will discuss options with the State prior to creation.

4.1.1.3.2 The product shall render accurate results (rate of 97% or higher) in under a minute.

Device accuracy varies based on drug configuration, with accuracy being specific to each drug strip. In accordance with what was stated in A46 of Amendment 4, the State is interested in overall product accuracy, which is to be taken as an average. The iCup Dx device being offered by RTL for the 6-drug line item described above has an average accuracy rate of 97.2%. Please see the package insert we have provided with this bid response for more detailed accuracy information by drug.

In accordance with what was stated in A36 of Amendment 4, the state will accept results that are available within 5 minutes. The iCup Dx device being offered will produce results in 5 minutes or less.

For sections 4.1.1.3.3 through 4.1.1.3.14, please see our responses to section 4.1.1.1. The iCup DX product offered by Redwood meets the same specifications.

Please note that RTL is currently waiting for more inventory of the iCup Dx to arrive. We anticipate this cup to be available by mid-November. Should the DOC award the bid and desire cups prior to the arrival of this stock, we would offer our 12- and 13-drug iCup options in the interim. Please see our Additional Optional Pricing Schedule for details on these cup configurations.

4.1.1.4 Panel Saliva Test for oral fluids 6 panel

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

RTL will provide the State with an upgraded 11 panel **UScreen Oral fluid Device Drug Test Device** to meet the drug configuration requested above. The specific oral fluid device we are offering, RTL part number 015010006, contains the following configuration: ALCO 0.02 / THC50 / COC20 / OPI40 / MAMP50 / BAR50 / BZO10 / BUP5 / MTD30 / OXY20. RTL can also offer a 6-drug Alere iScreen® OFD and a 6-drug OrAlert OFD as available device options, but these will have different configurations than the one requested above. The iScreen OFD and OrAlert would be offered at reduced prices.

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

All oral fluid rapid test devices offered are easy-to-use, portable testing devices that can be used anywhere, at any time, eliminating privacy concerns and same sex collector issues.

4.1.1.4.3 The product shall render accurate results (rate of 97% or higher) in under a minute.

Please see the attached product inserts for information about performance.

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

The oral fluid devices offered are all-inclusive and self-contained. No other supplies or chemicals are need to perform testing. RTL drug testing kits do not require electricity, special plumbing, instrumentation, calibration, a laboratory environment or refrigeration in order to be used. Testing kits are completely portable and are ready for immediate use in any location.

4.1.1.4.5 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.

Our oral fluid devices have easy-to-read results. A colored band appearing in the control region (C) is considered an internal positive procedural control, confirming sufficient specimen volume and correct procedural technique. Negative or positive results are indicated based on the presence or absence of a colored band in the test region (T). Detailed instructions for use are available in the product inserts attached to this bid response.

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

Oral fluid devices (OFDs) offered by RTL have the ability to detect drugs indicated on the panel simultaneously.

4.1.1.4.7 The Product shall have a minimum 18 month shelf-life.

Per Addendum 4 A42, the State will accept a 12-month shelf life. RTL will provide the State with drug testing kits with a shelf-life of a minimum of 12 months from the time of delivery. Please note that devices should never be used beyond the date of expiration, which is printed on the packaging of the product.

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

In accordance with what was stated in A1 and A37 of amendment 4, the state is removing the CLIA cut off levels and the CLIA waived requirements for the oral fluid device line item.

4.1.1.4.9 The product shall be FDA approved for commercial distribution with an active 510K notification document.

In accordance with what was stated in A1 of amendment 4, the state is removing the requirement for the Oral Fluid Devices to be FDA cleared. Oral fluid rapid test devices are for forensic use only.

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

- Shipping Bag
- Shipping container that will hold a minimum of two (2) specimen cups
- Chain of custody form

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

- 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 (for sending in less than five specimens without accruing charge)

Next day air service of inbound specimens sent to RTL for testing is provided at no charge when 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. Please see the pricing form for shipping fees.

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

The oral fluid test device is individually packaged in a sealed foil pouch with the part number, expiration date and specific drug configuration and cutoffs.

4.1.1.4.12 The product shall have fast turn-around time from receipt of specimen (48 hours 2 negative, 72 hours positive).

RTL can provide confirmation testing on urine and oral fluid specimens for inmate testing. Once the specimen is received at the laboratory, turn-around time will be 24 to 48 hours for negative screen results by enzyme immunoassay (EIA), and 72 to 96 hours for confirmed negative or positive results by gas chromatography-mass spectrometry (GC-MS) or liquid chromatography-tandem mass spectrometry (LC-MS/MS). Please note that turnaround times exclude Sundays and federal holidays. Additional time may also be required if retesting is necessary for validation.

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

The oral fluid test device is individually packaged in a sealed foil pouch with the part number, expiration date and specific drug configuration and cutoffs.

4.2 Employment/Employee drug testing kits

For sections 4.2 through 4.2.4.14, please see our responses to section 4.1.1.

The only apparent difference in device requirements for the employment/employee testing as compared to the inmate and parolee testing was the request for SAMHSA cut-off levels as opposed to CLIA cut-off levels. However, per A29 on Addendum 4, it appears that the State is interested in the same cut-off levels we have provided for the inmate and parolee drug testing kits section as for the employment/employee section. As such, all items offered in section 4.1.1 match items requested in section 4.2.

4.3 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 changes 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.

RTL will provide training at no additional cost to the Agency. RTL offers a variety of useful training resources to our clients:

- Online training modules
- Webinar training
- On-location training

We encourage your agency to utilize online and webinar-based options, as they allow more flexibility for your staff.

The online modules are PDF or Flash presentations that provide information about rapid test device usage and results interpretation, specimen labeling, and packaging of specimens for shipment. These online training modules may be accessed via our website, performed at your convenience, and revisited as many times as you like. We also offer online training certification quizzes that your staff may take to ensure that they understand proper procedure and interpretation of on-site devices; when the quiz is completed successfully, the quiz-taker may print out a Certificate of Training Completion. You may review these resources on our website at https://www.redwoodtoxicology.com/devices/certificate_training.

For clients interested in RTL's laboratory services, we provide training on how to properly label and package specimens being sent to our laboratory for screening and confirmation testing. Additional information about how to label, package, and ship specimens to our laboratory, may be found on our website at https://www.redwoodtoxicology.com/resources/labeling_shipping.

Our webinar and on-location training options given by our trainer include a presentation on specimen collection, chain of custody procedures, specimen shipment to the lab, and reporting methods. A question and answer session will follow every presentation. Training supplies will be provided to training attendees with sample bottles, labels, and literature.

4.4 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.

Please see our descriptions of test devices in section 4.1 and 4.2.

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

RTL's urinalysis drug test devices are convenient and ready to use.

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

RTL's drug testing kits do not require mixing of reagents, pretreatments, or special handling of urine.

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

RTL's iCup A.D. drug testing kits are capable of producing results within five (5) minutes and results are stable for up to an hour. The iCup Dx device produces results within five (5) minutes and results should not be read after eight (8) minutes. The UScreen Oral Fluid Device has results ready at ten (10) minutes with results stable for twenty (20) minutes; the iScreen OFD has results ready at ten (10) minutes with results stable for one hour; and the OrAlert OFD should be read at nine (9) minutes.

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

RTL's kits have easy-to-read results.

4.5.4 Drug testing kit shall not require refrigeration.

None of the devices offered by RTL for this bid require refrigeration.

4.5.5 Drug testing kit must utilize colloidal gold technology.

The iCup A.D., iCup Dx, and iScreen OFD all utilize colloidal gold technology. All of the rapid tests provided are immunoassay based on the principle of competitive binding. Drugs that may be present in the specimen compete against their respective drug conjugate for binding sites on their specific antibody. Please see product inserts for more information.

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

The urine rapid test cups will have a temperature strip included on the outside of the cup to indicate whether or not the urine is within the normal temperature range.

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

The iCup A.D., iCup Dx, and UScreen Oral all have flat test surfaces so results can be photocopied.

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

All of the rapid test devices offered as part of this bid include built-in procedural controls that confirm sufficient specimen volume, adequate membrane wicking, and correct procedural technique.

4.5.9 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 is able to provide preprinted COC forms with requisition numbers and a self-adhesive peel-off label that includes a matching requisition number.

4.5.10 The label shall provide a place to enter collection time, date, and client initials.

The label on RTL's preprinted COC has a place for the client ID and collection date, and the security seal has a place for the client's initials. The Alere COC label provides a place for the date and donor's initials.

4.5.11 Packaging

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

As described previously, the kits will be provided in a sealed bag with lot number, expiration date, drugs and cut-off levels.

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

RTL will provide clear, sealable shipping bags and lab packs for shipping specimens to the laboratory for confirmation.

4.5.11.3 The name and location of each Division of Corrections facility is listed in Exhibit A. The Vendor shall provide the contract items, at contract price, to any additional DOC facility(s) that may open, or require equipment and supplies during the course of the contract.

RTL agrees to this requirement.

4.5.12 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

RTL agrees to provide these items.

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

RTL will provide confirmation via GC-MS or LC-MS/MS, depending on drug class. Alcohol (Ethanol) will be confirmed using gas chromatography-flame ionization detection (GC-FID). Gas chromatography with flame-ionization detection has become the gold standard for ethanol analysis because of its ease of

automation, sensitivity, accuracy, and relative specificity. Alere Toxicology will use GC-MS for employee testing confirmations.

4.5.14 The confirmation laboratory shall be currently certified and maintain certification by the US Department of Health and Human Services (HHS) for all confirmations; Clinical Laboratory Improvement Amendments (CLIA) for inmate confirmations, and Substance Abuse Mental Health Administration (SAMSHA), to meet the standards for federal workplace drug testing programs for employment and parolee offender revocations. A copy of the certification should be provided with the bid.

RTL is certified by CLIA and will provide inmate confirmations; Alere Toxicology is certified by SAMHSA and will provide employment and parolee offender revocation tests.

4.5.15 The confirmation laboratory may, for inmate testing, be performed by certified Clinical Laboratory Improvement Amendments (CLIA) licensed laboratories; however, the Agency retains the requirement for SAMSHA lab testing for employee and pre-employment screenings. In addition, Agency will utilize SAMSHA lab testing for all parole revocations.

Please see our response to 4.5.14.

4.5.16 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 agrees to provide notification.

4.5.17 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).

Inmates and Parolee Offenders: The purpose of this testing is for criminal justice purposes and the Agency does not use administrative cutoffs for workplace testing. As such, the Agency requires that the confirmation lab test to limit of detection (LOD), which are 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 therefrom for both institutional discipline and probation revocation proceeding.

RTL will provide testing at industry standard levels of detection accepted under CLIA and will perform testing in accordance with CLIA protocols.

Civilian Pre-employment and Staff "For Cause" Drug Testing: The confirmation testing for this category shall be conducted in compliance with the Guidelines for Federal Workplace Drug Testing Programs. These Guidelines can be located at: https:/lwww.federalregister.gov/articles/20 *16/06/30120* 16-1 5469/mandatoryguidelines-for-federal-workplace-drug-testing-programs

Alere Toxicology will provide pre-employment testing in compliance with Federal Workplace Drug Testing Programs standards, in accordance with SAMHSA protocols.

4.5.18 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.

RTL will provide an EtG screen by enzyme immunoassay (EIA) with positive screens going to confirmation for EtG and EtS by liquid chromatography/tandem mass spectrometry (LC-MS/MS). Please see our additional pricing schedule for other EtG options.

4.5.19 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.

RTL can provide EtG screening at 100 ng/mL or 500 ng/mL, depending on the State's needs; EtG/EtS confirmation will be performed with a 100 ng/mL cut-off level.

4.5.20 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 will provide overnight delivery options for shipping specimens to our laboratory or Alere Toxciology's laboratory for testing.

4.5.21 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 these storage requirements.

4.6 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 a conflict of interest for a SAMHSA-certified lab to have an MRO on staff. We can provide a list of MROs who are certified and have used Alere Toxicology's reporting system for other clients. Utilizing a local MRO within the state would allow less travel time to court, if needed. ***Please note that MRO fees will be separate from the prices we have provided in this bid and negotiated directly between the State and the chosen MRO.***

For court services provided by the laboratory, we can provide expert witness services through written affidavit, telephonically, or in-court. Written affidavits are available for one hundred ($100.00) dollars, and telephonic testimony is available at a cost of two hundred and fifty ($250.00) dollars. RTL will also provide clients with court representation/ testimony at the cost per hour indicated on the bid form, which will include travel (as required by the bid). 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).

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

RTL agrees to provide the State with the most current version of each drug testing kit.

REDWOOD TOXICOLOGY LABORATORY

Confidence in testing.

Exceptions to Terms and Conditions

Although RTL agrees to the majority of West Virginia Department of Corrections' terms and conditions, we would like to request a few modifications as recommended by our legal counsel. If any of these requested modifications would disqualify us for consideration we would be happy to discuss further. However we are hopeful that the County will allow the following changes:

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26. ASSIGNMENT: Neither this Contract nor any monies due, or to become due hereunder, may be assigned by the Vendor without the express written consent, such consent shall not be unreasonably withheld, of the Agency, the Purchasing Division, the Attorney General's office (as to form only), and any other government agency or office that may be required to approve such assignments. Notwithstanding the foregoing, Purchasing Division approval mayor may not be required on certain agency delegated or exempt purchases.

36. INDEMNIFICATION: The Vendor agrees to indemnify, defend, and hold harmless the State and the Agency, their officers, and employees from and against: (1) Any third-party claims or losses for services rendered by any subcontractor, person, or firm performing or supplying services, materials, or supplies in connection with the performance of the Contract; (2) Any third-party claims or losses resulting to any person or entity injured or damaged by the Vendor, its officers, employees, or subcontractors by the publication, translation, reproduction, delivery, performance, use, or disposition of any data used under the Contract in a manner not authorized by the Contract, or by Federal or State statutes or regulations; and (3) Any failure of the Vendor, its officers, employees, or subcontractors to observe State and Federal laws including, but not limited to, labor and wage and hour laws.

Despite the above, in no event shall contractor be obligated to indemnify defend and save harmless the State and the Agency, their officers, agents and employees to the extent that any action claim or loss occurs or results, in whole or in part, from the acts or omissions of the State and the Agency, their officers, agents and employees or third parties.

REDWOOD TOXICOLOGY LABORATORY

Confidence in testing.

RTL References

Reference #1

Name of Reference Company	West Virginia Supreme Court of Appeals	
Address of Reference Company	1900 Kanawha BLVD E, RM E-100 Building 1 Charleston, WV 25305	
Reference Contact Person Information	Name:	Michael B. Lacy, Director
	Title:	Division of Probation Services
	Phone:	304-558-0145
	Email Address:	mikelacey@courtswv.gov

Reference #2

Name of Reference Company	Indiana Department of Correction	
Address of Reference Company	302 W. Washington St., Room E334 Indianapolis, IN 46204	
Reference Contact Person Information	Name:	Nicholas Law
	Title:	Director of Contracts
	Phone:	317-232-5672
	Email Address:	nlaw@doc.in.gov

Reference #3

Name of Reference Company	Help at Home	
Address of Reference Company	833 W. Lincoln Highway, Suite 200 East Schererville, IN 46375	
Reference Contact Person Information	Name:	Rick Cantrell
	Title:	Vice President
	Phone:	219-322-2730
	Email Address:	rcantrell@helpathome.com

State of California Department of Public Health

CLINICAL LABORATORY LICENSE

In accordance with the provisions of Chapter 3, Division 2 of the Business and Professions Code, the persons named below are hereby issued a license authorizing operation of a clinical laboratory at the indicated address or other site(s) on file with the department.

REDWOOD TOXICOLOGY LABORATORY, INC.
3650 WESTWIND BOULEVARD
SANTA ROSA CA 95403

OWNER(S):
REDWOOD TOXICOLOGY LABORATORY, INC.
RTL HOLDINGS, INC.
IVERNESS MEDICAL INNOVATIONS, INC.
ROBERT MOUNT
ALBERT BERGER
JOHN BRIGDEN

DIRECTOR(S):
MARK J DE MEO MD
RICHARD R WILBER MD

Lab ID Number: CLF 00003738
Effective Date: February 27, 2016
Valid Until: February 25, 2017
CLIA Number: 05D0707588

Robert J. Thomas

Robert J. Thomas, Acting Branch Chief
Laboratory Field Services

CENTERS FOR MEDICARE & MEDICAID SERVICES

CLINICAL LABORATORY IMPROVEMENT AMENDMENTS

CERTIFICATE OF COMPLIANCE

LABORATORY NAME AND ADDRESS

REDWOOD TOXICOLOGY LABORATORY,INC
3650 WESTWIND BLVD
SANTA ROSA, CA 95403-1066

CLIA ID NUMBER

05D0707588

EFFECTIVE DATE

10/14/2014

LABORATORY DIRECTOR

MARK DE MEO MD DIRECTOR

EXPIRATION DATE

10/13/2016

Pursuant to Section 353 of the Public Health Services Act (42 U.S.C. 263a) as revised by the Clinical Laboratory Improvement Amendments (CLIA), the above named laboratory located at the address shown hereon (and other approved locations) may accept human specimens for the purposes of performing laboratory examinations or procedures.

This certificate shall be valid until the expiration date above, but is subject to revocation, suspension, limitation, or other sanctions for violation of the Act or the regulations promulgated thereunder.

CMS
CENTERS FOR MEDICARE & MEDICAID SERVICES

Judith A. Yost, Director
Division of Laboratory Services
Survey and Certification Group
Center for Clinical Standards and Quality

356 Certs2_100714

If you currently hold a Certificate of Compliance or Certificate of Accreditation, below is a list of the laboratory specialties/subspecialties you are certified to perform and their effective date:

LAB CERTIFICATION (CODE)	EFFECTIVE DATE	LAB CERTIFICATION (CODE)	EFFECTIVE DATE
TOXICOLOGY (340)	10/14/1994		

Certificate of Accreditation

Substance Abuse and Mental Health Services Administration
SAMHSA
www.samhsa.gov • 1-877-SAMHSA-7 (1-877-726-4727)

The Substance Abuse and Mental Health Services Administration

certifies that

Redwood Toxicology Laboratory

Santa Rosa, CA

NLCP Laboratory Number: 0658

has successfully completed the requirements of the National Laboratory Certification Program for urine laboratories in accordance with the Mandatory Guidelines for Federal Workplace Drug Testing Programs.

Effective October 12, 2012

Pamela S. Hyde, J.D.
Administrator
Substance Abuse and Mental Health Services Administration

DEPARTMENT OF HEALTH & HUMAN SERVICES • USA

Frances M. Harding
Director
Center for Substance Abuse Prevention

AMERICAN ASSOCIATION OF BIOANALYSTS

PROFICIENCY TESTING SERVICE

2016

CERTIFICATE OF PARTICIPATION

This certifies that

Redwood Toxicology Laboratory Inc.

is a participant in a continuous program
of quality control for laboratory testing.

THE AMERICAN ASSOCIATION OF BIOANALYSIS

AAB

AAB

Director

COLLEGE of AMERICAN PATHOLOGISTS

The College of American Pathologists recognizes

Redwood Toxicology Laboratory

71824-00-01

As a laboratory demonstrating continuous improvement in quality through participation in 2015 CAP Surveys, EXCEL®, and/or Anatomic Pathology Education Programs.

Richard C. Friedberg, MD, PhD, FCAP
President

COLLEGE of AMERICAN PATHOLOGISTS

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Redwood Toxicology Laboratory

71824-00-01

As a laboratory demonstrating continuous improvement in quality through participation in 2015 CAP Surveys, EXCEL®, and/or Anatomic Pathology Education Programs.

Richard C. Friedberg, MD, PhD, FCAP
President

Certificate of Accreditation

Substance Abuse and Mental Health Services Administration
SAMHSA
www.samhsa.gov • 1-877-SAMHSA-7 (1-877-726-4727)

The Substance Abuse and Mental Health Services Administration

certifies that

Alere Toxicology Services, Inc.

Richmond, VA

NLCP Laboratory Number: 0760

has successfully completed the requirements
of the National Laboratory Certification Program for urine laboratories in accordance
with the Mandatory Guidelines for Federal Workplace Drug Testing Programs.

Effective June 20, 1994

Pamela S. Hyde, J.D.
Administrator
Substance Abuse and Mental Health Services Administration

DEPARTMENT OF HEALTH & HUMAN SERVICES · USA

Frances M. Harding
Director
Center for Substance Abuse Prevention

Sumandeep Rana, M.Sc., Ph.D.
707 570 4332
srana@redwoodtoxicology.com

PROFESSIONAL SKILLS

- Over 15 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
- Familiar with 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)
Chair – SOFT Designer Drugs Committee
Guest Editor – SOFT Special Issue of the Journal of Analytical Toxicology (JAT 2015)
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)

- 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 150 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.
- Manage and direct the Redwood Toxicology SAMHSA laboratory. Perform SAMHSA Responsible Person (RP) duties as required.
- Make recommendations to the General Manager and the Chief Toxicologist 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 Chief Toxicologist or 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

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.
MBA, Executive Program from Sonoma State University (expected completion Feb 2016)

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

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

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).

David Austin Green, Ph.D., DABCC, FACB

Phone: 800-433-3823 / 504-361-8989
Email: david.green@alere.com

Curriculum Vitae

Work Experience:

Laboratory Director & Co-Responsible Person (RP) 2001 – Present
Substance Abuse Testing Division of Kroll, Gretna, Louisiana

Scientific Director 1997 –2000
Dynacare Laboratories, Baton Rouge, Louisiana

Scientific Director 1992 –1997
Louisiana Reference Laboratories, Baton Rouge, Louisiana

Technical Director 1988 –1992
SKBL (SmithKline) as Louisiana Reference Laboratories, Baton Rouge, Louisiana

Chemistry Manager 1987 –1988
International Clinical Laboratories as Louisiana Reference Laboratories, Baton Rouge, Louisiana

Director of Clinical Chemistry 1985 – 1986
Stroink Pathology Laboratory, Bloomington, Illinois

Postdoctoral Fellow 1984 – 1985
Louisiana State University and Louisiana Reference Laboratories, Baton Rouge, Louisiana

Instructor and Fellow 1982 – 1984
Louisiana State University Chemistry Department, Baton Rouge, Louisiana

Joint Appointment, Graduate School for Biomedical Sciences and Pharmacology Department 1980 – 1982
University of Texas Health Science Center, Houston, Texas

Teaching Assistant and Research Assistant 1975 – 1979
Texas A&M University Biochemistry Department, College Station, Texas

Professional Experience:

Inspector 2001 – present
National Laboratory Certification Program (NLCP)

As an inspector for the NLCP, I personally visit, audit, and report on other laboratories certified by the Substance Abuse and Mental Health Services Administration (SAMHSA) to ensure compliance with regulatory guidelines.

Inspector 1992 – present
College of American Pathologists Forensic Urine Drug Testing Program

As an inspector for the CAP-FUDT, I personally visit, audit, and report on other certified laboratories to ensure compliance with regulatory guidelines.

Faculty 1988 – 2000

Louisiana State University, Baton Rouge, Louisiana

Taught classes as part of a cooperative agreement to provide instruction and laboratory training for students in the Louisiana State University Medical Technology Program.

Outside Member 1996 – 1999

National Institutes of Health (NIH) Biological and Recombinant DNA Safety Committee

As a member of this committee, I was responsible for the review of all NIH grants made through Louisiana State University that might be deemed as a Public Health Hazard.

Specific Toxicology Training and Experience:

Beyond my Ph.D. degree in Biochemistry, my first postdoctoral position at the *University of Texas* included a joint appointment in the Pharmacology Department, where I was trained in the pharmacokinetics involved in drug absorption, metabolism, and elimination

During my tenure at *LSU/LRL,* I was trained in forensic drug testing including urine, blood, and a variety of other matrices (bile, stomach contents, etc.) collected for coroner cases. I proceeded to introduce and develop new methods to this and other departments.

At *Stroink Pathology Laboratories,* I managed the forensic toxicology laboratory in addition to other laboratory sections. At *International Clinical Laboratories (ICL)* and *SmithKline (SKBL),* I continued to manage a forensic laboratory along with my other responsibilities. Further, I introduced Gas Chromatography / Mass Spectrometry to the laboratory, developing and validating all of the methods necessary to be certified as a CAP-FUDT laboratory. Along with all sections of the clinical laboratory, I continued to manage the certified forensic laboratory.

Further, I was a member of the *ICL* forensic toxicology standardization committee chaired by Dr. Irving Sunshine. Our planning team standardized methods and design for the anticipated NLCP implementation. Additionally, I was a member of the Codification Committee for implementation of the State of Louisiana Forensic Drug Testing Law. The committee was charged with publishing a set of guidance documents to regulate the new drug testing law.

At *Kroll,* I serve as the Laboratory Director and Co-Responsible Person. As such, I manage all sections of the laboratory and am responsible for receipt, testing, and reporting of all results.

I have provided testimony in over 100 cases in various state and federal courts along with hearings for various agencies (such as workers' compensation and unemployment hearings). In these hearings, I served both as an expert in forensic toxicology and as witness to the laboratory findings. Additionally, I have served as an expert in pharmacology.

I have served and continue to serve as a lead inspector for the CAP-FUDT program for over 15 years and currently serve as an NLCP laboratory inspector.

Education:

Nicholls State University, Thibodeaux, Louisiana 1975

B.S. in Biology/Chemistry

Texas A&M University, College Station, Texas 1979
Ph.D. in Biochemistry

Honors:

- *Cum Laude*, Nicholls State University, 1975
- *Gamma Sigma Delta*, Texas A&M University Honor Society
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Memberships and Certifications:

American Association for Clinical Chemistry

Society of Forensic Toxicologists

American Academy of Forensic Sciences

Diplomate, American Board of Clinical Chemistry in Clinical Chemistry 1989

Diplomate, American Board of Clinical Chemistry in Toxicology 1992

Clinical Chemists Recognition Award 1992 ,2002,2008

Fellow, National Academy of Clinical Biochemistry 2002

Publications:

Papers:

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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

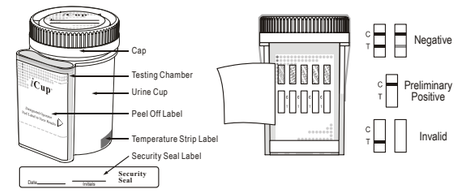
- A timer or any kind of a timing device such as a wrist watch is required to run this test.
- External controls

DIRECTIONS FOR USE

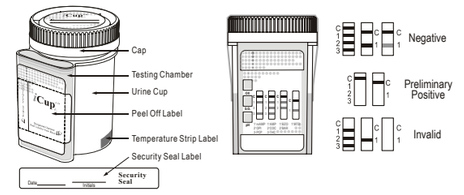
Allow the test cup, urine specimen, and/or controls to equilibrate to room temperature (15-30°C) prior to testing.

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.

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Manufactured for: Alere Toxicology Services-Products Division
Portsmouth, VA 23704 USA

*i*Cup® Dx 14 Step-by Step Instructions

The Alere *i*Cup® Dx 14 Drug Screen Cup is an *in vitro* screening test for the rapid detection of multiple drugs in human urine at or above the following cutoff concentration:

THC	11-nor-Δ9-Tetrahydrocannabinol-9-carboxylic acid	50 ng/ml
COC	Benzoylecgonine	150 ng/ml
OPI	Morphine	300 ng/ml
MET	d-Methamphetamine	500 ng/ml
AMP	d-Amphetamine	500 ng/ml
BZO	Oxazepam	300 ng/ml
BAR	Secobarbital	300 ng/ml
MTD	Methadone	300 ng/ml
BUPG	Buprenorphine Glucuronide	10 ng/ml
TCA	Nortriptyline	1000 ng/ml
MDMA	3,4-Methylenedioxymethamphetamine	500 ng/ml
OXY	Oxycodone	100 ng/ml
PCP	Phencyclidine	25 ng/ml
PPX	Propoxyphene	300 ng/ml

These tests provide visual qualitative results and are intended for *in vitro* diagnostic use only. The Alere *i*Cup® Dx 14 Drug Screen Cup is available in double drug analyte dip format. It is intended for prescription point-of-care use.

These tests provide only a preliminary test result and are the first step in a two-step process for detecting drugs of abuse in urine. The second step is confirming the results in a certified laboratory. For a quantitative result or to confirm preliminary positive results obtained by the Alere *i*Cup® Dx 14 Drug Screen Cup, a more specific alternative method such as Gas Chromatography/Mass Spectrometry (GC/MS) must be used. Clinical consideration and professional judgment must be applied to any drug of abuse test result, particularly when a preliminary positive result is indicated.

This is a preliminary screening test that detects drug-of-abuse in urine at specified detection levels. To confirm preliminary positive results, a more specific method such as Gas Chromatography/Mass Spectrometry (GC/MS) must be used.

CONTENTS OF KIT

For Testing:

- ✓ 1 Step-by-Step Test Instructions
- ✓ 25 Individually Wrapped Test Lids
- ✓ 25 Specimen Cups

Specimen Collection Cup

Individually Wrapped Test Lid

STORAGE

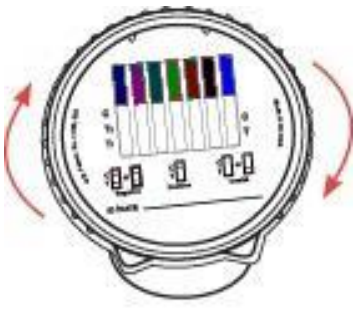
Store the Alere *i*Cup® Dx 14 at room temperature 59˚F to 86˚F (15˚C to 30˚C).

INSTRUCTION

Step 1.
Collect fresh urine in the specimen cup. Make sure the urine is **above the minimum line**.

Min. Line →

Open foil pouch. Remove test lid from pouch. Discard desiccant.



Step 2.
Twist the lid onto the cup. The cup lid must be closed tightly.

Step 3.
Tilt the cup on its legs to activate the test. **Read test results at 5 minutes. Do not read after 8 minutes.**

5 minutes

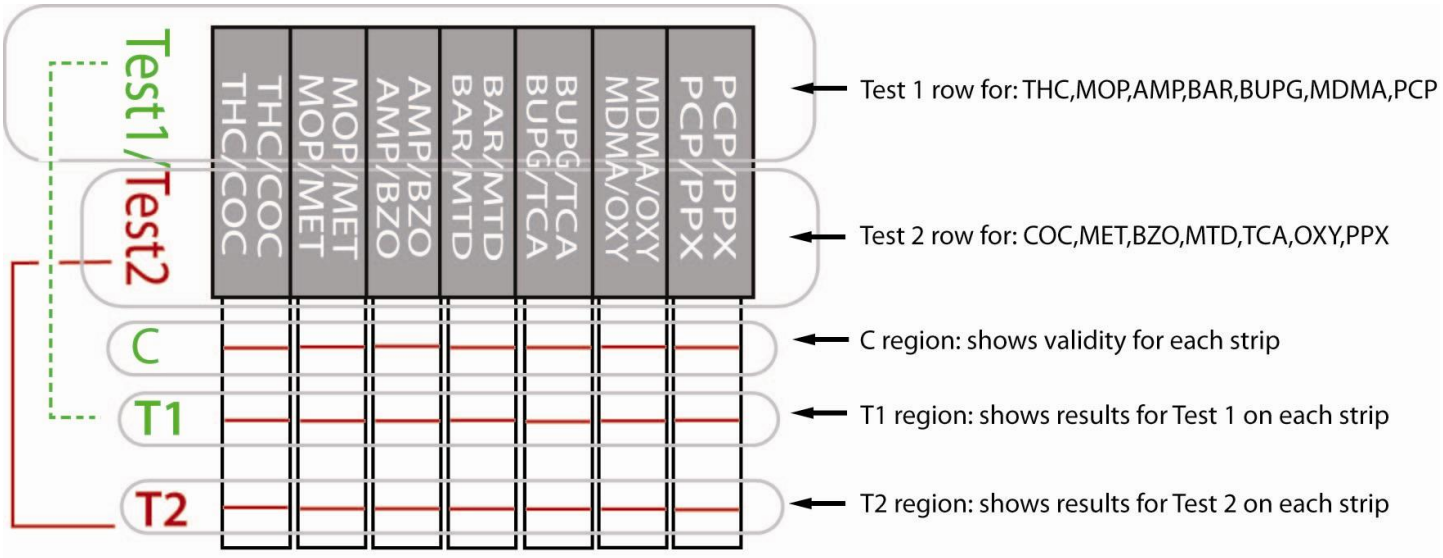
INTERPRETATION OF RESULTS

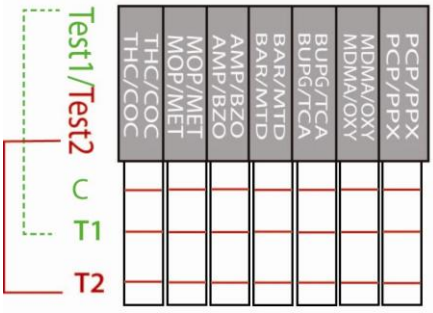
Each strip contains two drug tests. C region shows validity of a test result. T1 region shows result for Test 1. T2 region shows result for Test 2.

For C region:
The appearance of a line indicates a valid result.
No line means an **Invalid** result. If a test strip does not have a line in the C region, test results are **Invalid** for both T1 and T2 on that strip.

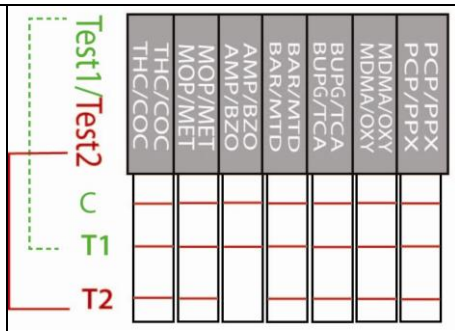
For T1 and T2 regions:
The appearance of a line indicates a **Negative** result.
Note: **Any test line, even a very faint test line, is considered a negative result.**

No line indicates a **Preliminary Positive** result.
Note: **Any urine with preliminary positive results should be sent to a laboratory for confirmation.**

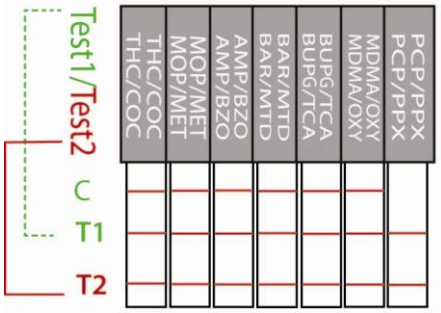




Example #1: There is a line appearing in both T1 and T2 regions on all test strips. Therefore, it is **Negative** for all tests.



Example #2: There is no line appearing in the T2 region on the third test strip. Therefore, it is **Preliminary Positive** for BZO test. All other tests are **Negative**.



Example #3: There is no line appearing in the C region on the seventh test strip. Therefore, it is **Invalid** for both PCP and PPX tests. All other tests are **Negative**.

DETECTION LEVEL

Illicit Drug	Identifier	Cut-off Level[1]
Marijuana	THC	50 ng/ml
Cocaine	COC	150 ng/ml
Opiates	MOP	300 ng/ml
Methamphetamine	MET	500 ng/ml
Amphetamine	AMP	500 ng/ml
Ecstacy	MDMA	500 ng/ml
Phencyclidine	PCP	25 ng/ml
Propoxyphene	PPX	300 ng/ml

Prescription Drug	Identifier	Cut-off Level[1]
Benzodiazepines	BZO	300 ng/ml
Barbiturates	BAR	300 ng/ml
Methadone	MTD	300 ng/ml
Buprenorphine	BUPG	10 ng/ml
Tricyclic Antidepressants	TCA	1000 ng/ml
Oxycodone	OXY	100 ng/ml

[1] Cut-off level is the lowest drug concentration in the urine that can be detected by the Alere *i*Cup® Dx 14.

WARNINGS AND PRECAUTIONS

- For *in vitro* diagnostic use only (not for internal use).
- The test is for one time use only. It is not reusable.
- Do not use the Alere *i*Cup® Dx 14 after the expiration date printed on the pouch.
- Keep the Alere *i*Cup® Dx 14 in its original sealed pouch until ready for use. Do not use the test if the pouch is ripped or torn.
- Certain foods or medications may cause the test to give false results.
- Contaminated or tainted urine sample may give false results.
- Send specimen with preliminary positive or uncertain results to a laboratory for confirmation.
- Urine may contain infectious diseases. Always wear gloves and wash hands with soap after handling.
- Do not use this test if you are color-blind.

LIMITATIONS OF THE TEST

- The assay is designed for use with human urine only.
- Positive results only indicate the presence of drug/metabolites and do not indicate or measure intoxication.
- There is a possibility that technical or procedural errors as well as other substances in certain foods and medication may interfere with the test and cause false results. See Specificity section for the list of substances that will produce positive results, and Interference section for list of compounds that do not interfere with test performance.
- If a drug/metabolite is found present in the urine specimen, the assay does not indicate frequency of drug use or distinguish between drugs of abuse and certain foods and/or medications.
- If it is suspected that the sample may have been mislabeled a new specimen should be collected.
- If it is suspected that the sample may have been tampered, a new specimen should be collected.

QUALITY CONTROL

Internal control: The Alere *i*Cup® DX 14 test device has built-in internal procedural controls. The appearance of the control band (C) is considered an internal procedural control. This band should always appear if adequate sample volume is used and the testing procedure is followed. Additionally, the background color should become clear and provide distinct test result. If the control band (C) does not appear then the test is invalid. The test should be repeated using a new device.

External control: It is recommended that negative and positive urine controls be used to initially test each new lot of product to ensure proper kit performance. The same assay procedure should be followed with external control materials as with a urine specimen. If external controls do not produce the expected results, do not run test specimens. Follow the proper federal, state and local guidelines when running external controls.

Quality control testing at regular intervals is a good laboratory practice and may be required by federal, state or local guidelines. Always check with the appropriate licensing or accrediting bodies to ensure that the quality program employed meets the established standards.

PERFORMANCE CHARACTERISITCS

PRECISION

A study was conducted at two laboratories and one physician office in an effort to determine the precision of the Alere *i*Cup® DX 14 over 12 or more consecutive days. Testing was conducted on the Amphetamine, Barbiturates, Benzodiazepines, Buprenorphine, Cocaine, Marijuana, Methamphetamine, Methylenedioxymethamphetamine, Methadone, Opiates, Oxycodone, Phencyclidine, Propoxyphene, and Tricyclic Antidepressants assays by operators 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 the concentration of ± 50% cut-off level was labeled as a blind and tested at each site. The correlation with expected results was >99% across all lots and sites (with a 95% confidence interval).

ACCURACY

The accuracy of the Alere *i*Cup® Dx 14 was evaluated in comparison to the results from GC/MS or LC/MS analysis. Thirty-six (36) negative drug-free urine samples were collected from volunteer donors and tested with both the Alere *i*Cup® Dx 14 and the GC/MS or LC/MS method. Of the 36 negative urine samples tested, all were found negative by both methods. Additionally, for each drug test, a minimum of 40 clinical urine samples previously analyzed by GC/MS or LC/MS method with known concentration(s) of drug(s) values were blind labeled and evaluated. The results are summarized below:

Drug Test		GC/MS Neg.	GC/MS < -50%	GC/MS -50% to Cutoff	GC/MS Cutoff to +50%	GC/MS > +50%	% Agreement w/ GC/MS	
							Neg (-)	Pos (+)
THC 50	Pos. (+)	0	0	1	6	35	97.7%	100%
	Neg. (-)	36	2	4	0	0		
COC 150	Pos. (+)	0	0	3	3	37	92.7%	97.6%
	Neg. (-)	36	0	2	1	0		
MOP 300	Pos. (+)	0	0	3	7	34	92.5%	100%
	Neg. (-)	36	0	1	0	0		
MET 500	Pos. (+)	0	0	0	5	67	100%	96.0%
	Neg. (-)	36	2	4	3	0		
AMP 500	Pos. (+)	0	0	2	5	36	95.1%	100%
	Neg. (-)	36	1	2	0	0		
BZO 300	Pos. (+)	0	0	3	4	39	92.5%	100%
	Neg. (-)	36	0	1	0	0		
BAR 300	Pos. (+)	0	0	1	6	33	97.5%	95.1%
	Neg. (-)	36	0	3	2	0		
MTD 300	Pos. (+)	0	0	0	3	36	100%	97.5%
	Neg. (-)	36	0	4	1	0		
BUPG 10	Pos. (+)	0	0	1	4	38	97.5%	97.7%
	Neg. (-)	36	0	3	1	0		
TCA 1000	Pos. (+)	0	0	0	27	11	100%	92.7%
	Neg. (-)	36	0	4	3	0		
MDMA 500	Pos. (+)	0	0	1	3	40	97.5%	97.7%
	Neg. (-)	36	0	3	1	0		
OXY 100	Pos. (+)	0	0	2	6	38	95.2%	100%
	Neg. (-)	36	0	4	0	0		
PCP 25	Pos. (+)	0	0	0	3	36	100%	95.1%
	Neg. (-)	36	0	4	2	0		
PPX 300	Pos. (+)	0	0	2	4	36	95.0%	100%
	Neg. (-)	36	0	2	0	0		

SPECIFICITY

The specificity for the Alere *i*Cup® Dx 14 was determined by testing various drugs, drug metabolites, structurally related compounds, and other compounds that are likely to be present in urine. All compounds were prepared in drug-free normal human urine. The effect of specimens with various pH (4.5–9) and specific gravity (1.005–1.030) ranges was also evaluated and found not to interfere with the Alere *i*Cup® Dx 14.

The following compounds produced positive results when tested at or above the concentrations listed below.

AMP 500 ng/ml

Compound	ng/ml	Compound	ng/ml
d-Amphetamine	500	Phentermine	1,000
l-Amphetamine	20,000	β-Phenylethylamine	80,000
d,l-3,4-MDA	1,500		

BAR 300 ng/ml

Compound	ng/ml	Compound	ng/ml
Allobarbital	1,500	Butalbital	300
Alphenal	400	Butethal	400
Amobarbital	1,500	Pentobarbital	400
Aprobarbital	400	Phenobarbital	400
Barbital	400	Secobarbital	300
Butabarbital	400		

BZO 300 ng/ml

Compound	ng/ml	Compound	ng/ml
α-Hydroxy Alprazolam	50	Lorazepam	1,500
Alprazolam	150	Lormetazepam	1,000
Bromazepam	800	Medazepam	2,000
Chlordiazepoxide	2,000	Nitrazepam	1,000
Clobazam	200	Nordiazepam	100
Clonazepam	4,000	Oxazepam	300
Delorazepam	6,000	Phenazepam	1,000
Diazepam	150	Prazepam	1,000
Estazolam	300	Temazepam	150
Flunitrazepam	1,000	Triazolam	1,500
Flurazepam	300		

BUPG 10ng/ml

Compound	ng/ml	Compound	ng/ml
Buprenorphine	100	Norbuprenorphine	100
Buprenorphine Glucuronide	10	Norbuprenorphine Glucuronide	100

COC 150 ng/ml

Compound	ng/ml	Compound	ng/ml
Benzoylecgonine	150	Ecgonine	65,000

MDMA 500 ng/ml

Compound	ng/ml	Compound	ng/ml
d,l-3,4-MDA	2,000	d,l-3,4-MDMA	500
d,l-3,4-MDEA	250	d-Methamphetamine	50,000

MET 500 ng/ml

Compound	ng/ml	Compound	ng/ml
Ephedrine	10,000	d-Methamphetamine	500
p-Hydroxymethamphetamine	1,750	l-Methamphetamine	25,000
d,l-3,4-MDMA	1,000	Procaine	50,000
d,l-3,4-MDEA	20,000	Trimethobenzamide	75,000

MTD 300 ng/ml

Compound	ng/ml	Compound	ng/ml
Doxylamine	50,000	Methadone	300
2-Ethylidene-1,5-Dimethyl-1-3,3-Diphenylpyrolidine	50,000	Pheniramine	75,000

MOP 300 ng/ml

Compound	ng/ml	Compound	ng/ml
6-Acetylmorphine	500	Hydrocodone	1,000
6-Acetylcodeine	600	Hydromorphone	400
Codeine	300	Morphine	300
Dihydrocodeine	500	Morphine-3-β-D-Glucuronide	500
Ethyl morphine	300	Nalorphine	5,000
Heroin	100		

OXY 100 ng/ml

Compound	ng/ml	Compound	ng/ml
6-Acetylcodeine	15,000	Oxymorphone	3,000
Codeine	5,000	Oxycodone	100
Dihydrocodeine	2,000	Hydromorphone	25,000
Hydrocodone	300	Ethyl Morphine	5,000

PCP 25 ng/ml

Compound	ng/ml	Compound	ng/ml
4-Hydroxy Phencyclidine	500	Phencyclidine	25
Metaphit	500	Phencyclidine Morpholine	50,000

PPX 300ng/ml

Compound	ng/ml	Compound	ng/ml
Propoxyphene	300	Norpropoxyphene	500

TCA 1000 ng/ml

Compound	ng/ml	Compound	ng/ml
Amitriptyline	1,000	Nordoxepin	1,000
Clomipramine	7,500	Nortriptyline	1,000
Cyclobenzaprine	1,500	Perphenazine	50,000
Desipramine	750	Promazine	10,000
Doxepin	1,000	Protriptyline	350
Imipramine	750	Trimipramine	1,500

THC 50 ng/ml

Compound	ng/ml	Compound	ng/ml
Cannabidiol	100,000	11-Hydroxy-Δ9-THC	2,500
Cannabinol	50,000	Δ-8-Tetrahydrocannabinol	7,000
11-nor-Δ8-THC-9-COOH	50	Δ-9-Tetrahydrocannabinol	10,500
11-nor-Δ9-THC-9-COOH	50		

CONSUMER STUDY

A consumer study was conducted to determine the performance of the device when used by untrained, laypersons following only the instructions in the product labeling. A total of 153 participants read a total of 5460 assays during the study and 5228 of those 5460 assays (95.8%) was interpreted correctly. Each assay was tested by these participants using spiked solutions targeted to 0%, 25%, 50%, 75%, 125%, 150%, and 175% of the assay cutoff level.

INTERFERENCE

The following compounds were found not to cross-react when tested at concentrations up to 100 µg/ml (100,000 ng/ml).

Acetaminophen
Acetone
Acetylsalicylic acid (Aspirin)
6-Acetylcodeine *(except MOP & OXY assay)*
6-Acetylmorphine *(except MOP assay)*
Amoxicillin
Albumin
Allobarbital *(except BAR assay)*
Alphenal *(except BAR assay)*
Alprazolam *(except BZO assay)*
Amitriptyline *(except TCA assay)*
Amobarbital *(except BAR assay)*
Amoxapine
d-Amphetamine *(except AMP assay)*
l-Amphetamine *(except AMP assay)*
Ampicillin
Apomorphine
Aprobarbital *(except BAR assay)*
l-Ascorbic Acid (Vitamin C)
Aspartame
Atropine
Barbital *(except BAR assay)*
Benzilic acid
Benzocaine (Ethyl p-Aminobenzoate)
Benzoic acid
Benzoylecgonine *(except COC assay)*
Benzphetamine
Bilirubin
Bromazepam *(except BZO assay)*
d-Brompheniramine
Buprenorphine *(except BUPG assay)*
Butabarbital *(except BAR assay)*
Butalbital *(except BAR assay)*
Butethal *(except BAR assay)*
Caffeine
Cannabidiol *(except THC assay)*
Cannabinol *(except THC assay)*
Chlordiazepoxide *(except BZO assay)*
Chloroquine
d,l-Chlorpheniramine
Chlorpromazine
Cholesterol
Clobazam *(except BZO assay)*
Clomipramine *(except TCA assay)*
Clonazepam *(except BZO assay)*
Cocaine
Codeine *(except MOP & OXY assays)*
Cortisone
l-Cotinine
Creatine
Creatinine
Cyclobenzaprine *(except TCA assay)*
Delorazepam *(except BZO assay)*
Deoxycorticosterone
Desipramine *(except TCA assay)*
Dextromethorphan
Diazepam *(except BZO assay)*
Dihydrocodeine *(except MOP & OXY assay)*
4-Dimethylaminoantipyrine
Diphenhydramine
Dopamine (3-Hydroxytyramine)
Doxepin *(except TCA assay)*
Doxylamine *(except MTD assay)*
Ecgonine *(except COC assay)*
Ecgonine Methyl Ester
l-Epinephrine
d,l-Ephedrine *(except MET assay)*
Erythromycin
Estazolam *(except BZO assay)*
β-Estradiol
Estrone-3-Sulfate
Ethanol
Ethyl Morphine *(except MOP & OXY assay)*
Ethyl-p-aminobenzoate
2-Ethylidene-1,5-Dimethyl-1-3,3-Diphenylpyrolidone *(except MTD assay)*
Flunitrazepam *(except BZO assay)*
Flurazepam *(except BZO assay)*
Furosemide
Glucose
Gentisic acid
Glutethimide
Guaiacol Glyceryl Ether
Hemoglobin Heroin *(except MOP assay)*
Hippuric acid
Hydrochlorothizide
Hydrocodone *(except MOP & OXY assays)*
Hydrocortisone
Hydromorphone *(except MOP & OXY assays)*
α-Hydroxy Alprazolam *(except BZO assay)*
4-Hydroxy Phencyclidine *(except PCP assay)*
p-Hydroxymethamphetamine *(except MET assay)*
11-Hydroxy-Δ-9-THC *(except THC assay)*
Ibuprofen
Imipramine *(except TCA assay)*
d,l-Isoproterenol
Ketamine
Lidocaine
Lorazepam *(except BZO assay)*
Lormetazepam *(except BZO assay)*
Medazepam *(except BZO assay)*
Meperidine
Metaphit *(except PCP assay)*
Methadone *(except MTD assay)*
d-Methamphetamine *(except MET & MDMA assay)*
l-Methamphetamine *(except MET assay)*
Methaqualone
Methoxyphenamine
(1R,2S) N-Methyl-Ephedrine
2-Methylamine-Propiophenone
d,l-3,4-Methylenedioxyamphetamine *(except AMP & MDMA assays)*
d,l-3,4-methylenedioxyethylamphet *(except MET & MDMA assays)*
d,l-3,4-Methylenedioxymethamphetamine *(except MET& MDMA assays)*
Methylphenidate
Morphine *(except MOP assay)*
Morphine-3-ß-D-Glucuronide *(except MOP assay)*
Nalidixic acid
Nalorphine *(except for MOP assay)*
Naloxone
d-Naproxen
Niacinamide
Nitrazepam *(except BZO assay)*
Nordiazepam *(except BZO assay)*
Nordoxepin *(except TCA assay)*
Nicotine, (S)-
Norepinephrine
Norethindrone
Norpropoxyphene *(except PPX assay)*
Nortriptyline *(except TCA assay)*
Oxalic Acid
Oxazepam *(except BZO assay)*
Oxolinic acid
Oxycodone *(except OXY assay)*
Oxymorphone *(except OXY assay)*
Papaverine
Penicillin-G (Benzylpenicillin)
Pentazocine
Pentobarbital *(except BAR assay)*
Perphenazine *(except TCA assay)*
Phenazepam *(except BZO assay)*
Phencyclidine *(except PCP assay)*
Phencyclidine Morpholine *(except PCP assay)*
Pheniramine *(except MTD assay)*
Phenobarbital *(except BAR assay)*
Phenothiazine (Thiodiphenylamine)
Phentermine *(except AMP assay)*
Phenylephrine
β-Phenylethylamine *(except AMP assay)*
Prednisolone
Prazepam *(except BZO assay)*
Procaine *(except MET assay)*
Promazine *(except TCA assay)*
Promethazine
Propoxyphene *(except PPX assay)*

Protriptyline *(except TCA assay)*
d-Pseudoephedrine
Pyrrolidine
Quinidine
Quinine
Ranitidine
Riboflavin
Salicylic acid
Secobarbital *(except BAR assay)*
Serotonin
Sertraline
Sodium Chloride
Sulfamethazine
Sulindac
Temazepam *(except BZO assay)*
Tetracycline
Δ8-THC *(except THC assay)*
Δ9-THC *(except THC assay)*
11-nor-Δ8-THC-9-Carboxylic Acid *(except THC assay)*
11-nor-Δ-9-THC-9-Carboxylic Acid *(except THC assay)*
Thiamine
Thioridazine
Triazolam *(except BZO assay)*
Trifluoperazine
Trimethobenzamide *(except MET assay)*
Trimipramine *(except TCA assay)*
Tryptamine
d,l-Tryptophan
Tyramine
d,l-Tyrosine
Uric Acid
Verapamil
Zomepirac

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Part No.: PI-X11-I-DXA Rev: A, 06/2014

For Forensic Use Only!

UScreen Oral

ON-SITE SALIVA DRUG TEST

The UScreen Oral Fluids Drug Test is a drug testing device that detects up to 12 drugs of abuse. In addition, the UScreen Oral can be ordered with an available test for alcohol. This saliva drug test provides results in minutes, and being an oral fluid test, it provides extra security since specimens can't be tampered with or substituted.

UScreen Oral Features

- Market-leading drug cutoffs
- One strip per drug for ease of use
- Tests for up to 16 Drugs
- Available with alcohol test strip
- Donor cannot defeat test
- Eliminates cross gender issues

UScreen Oral Device Tests Available For:

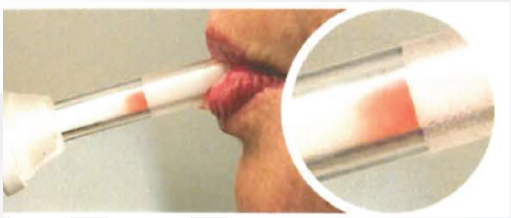
Amphetamine	(AMP)	Methamphetamine	(MET)
Barbiturate	(BAR)	Ecstasy	(MDMA)
Benzodiazepine	(BZO)	Opiates	(OPI)
Buprenorphine	(BUP)	Oxycodone	(OXY)
Cocaine	(COC)	Phencyclidine	(PCP)
Cotinine	(COT)	Propoxyphene	(PPX)
EDDP	(EDDP)	Marijuana	(THC)
Ketamine	(KET)	K2/Spice	
Methadone	(MTD)	Alcohol	

Using The UScreen Oral Drug Test

IMPORTANT: Donors should not place anything (including food, drink - including water, gum or tobacco products) in their mouth for at least 10 minutes prior to the procedure. *DO NOT BITE, SUCK OR CHEW ON THE SPONGE!* Refrain from talking while collection swab is in the mouth.

Step 1

Have the donor sweep the inside of mouth (cheeks, tongue, gums) several times with the collection swab. Continue to hold in closed mouth until color on the saturation indicator strip appears in the indicator window. Once color appears in indicator window, donor may remove swab from mouth.



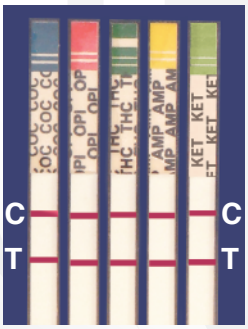
Step 2

Once swab is saturated, insert the collection device, sponge-first, into the screening device, screwing the cap down until it clicks. Once locked in place, it is airtight, tamper evident, and ready to dispose of after use - or send to lab for confirmation (on non-negative results). Ensure that specimen is contacting all test strips. If not, rotate the device side to side/ front to back to disperse the specimen within the chamber. With specimen dispersed, set device upright on flat surface. Keep upright while test runs.

Step 3

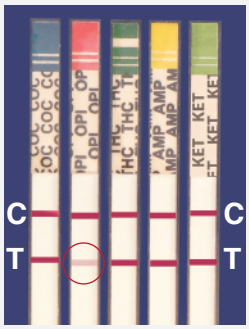
Reading the Results

Read the results when all upper “Control” or “C” lines have appeared. Negative results can be read as soon as all “Test” lines are visible. (Wait 5 minutes to determine a Positive Result.)



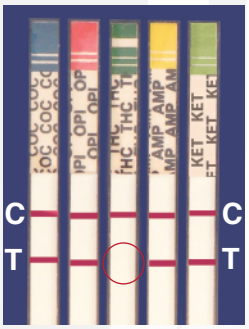
Negative

A negative result is indicated by the presence of the lower “Test” Line for each designated drug.



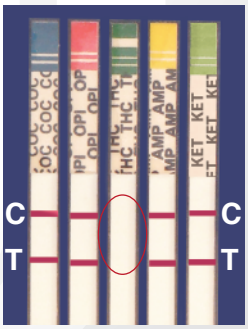
Negative

The presence of even a very light “Test” Line indicates a negative result.



Positive

A positive result is indicated by the absence of the lower “Test” Line for a specific drug. Wait 5 minutes to determine a positive result.



Invalid

An invalid result is indicated by the absence of the upper “Control” or “C” Line. If this occurs run a second test.

C-S17 Oral Screen Saliva Drug Test

INTENDED USE

The Oral Screen Saliva Drug Test is a rapid visual immunoassay for the qualitative detection of drugs of abuse in human oral fluid specimens. The test system consists of up to 16 membrane strips mounted in a plastic device. 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
Barbiturate(BAR)	Barbiturate	50
Benzodiazepine (BZO)	Oxazepam	10
Buprenorphine(BUP)	Buprenorphine	5
Cocaine (COC)	Cocaine	20
Cotinine(COT)	Cotinine	50
EDDP(EDDP)	2-Ethyliden-1,5-Dimethyl-3,3-Diphenylpyrrolidine	20
Ketamine（KET）	Ketamine	50
Methadone (MTD)	Methadone	30
Methamphetamine (MET)	D-Methamphetamine	50
Ecstasy（MDMA）	3,4-Methylenedioxymethamphetamine	50
6-MAM	6-Monoacetylmorphine	25
Opiates (OPI)	Morphine	40
Opiates (OPI)	Morphine	25
Oxycodone(OXY)	Oxycodone	40
Phencyclidine (PCP)	Phencyclidine	10
Propoxyphene(PPX)	Propoxyphene	50
Marijuana (THC)	11-nor-Δ^9-THC-9-COOH	12
Marijuana (THC)	Δ^9-THC	50

PRINCIPLE

The Oral Screen Saliva Drug Test 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 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.

MATERIALS

Materials Provided

Individually packed screening devices
Oral fluid collection swabs
Package insert

Materials Required but Not provided

Timer
Positive and negative controls

PRECAUTIONS

- For professional *in vitro* diagnostic 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.
- Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed.

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.

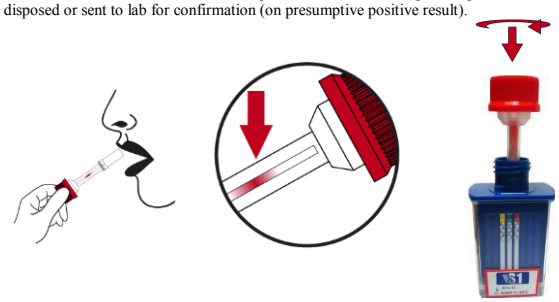
SPECIMEN COLLECTION AND STORAGE

- The Oral Screen Saliva Drug Test 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

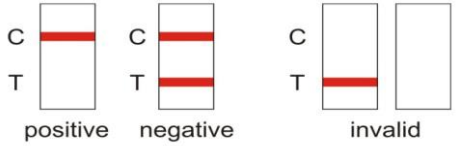
Bring tests, specimens, and/or controls to room temperature (15-30°C) before use. Donors should avoid placing anything (including food, drink, gum and tobacco products) in their mouth for at least 10 minutes prior to specimen collection.

- The oral fluid specimen should be collected using the collector provided with the kit. No other collection devices should be used with this assay.
- 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.
- Bring tests, specimens, and/or controls to room temperature (15-30°C) before use.
- Using the provided collection swab, have donor sweep inside of mouth (cheek, gums, and tongue) several times, and then hold swab in mouth until color on the saturation indicator strip appears in the indicator window of collection swab. Important: Do not bite, suck, or chew on the sponge.
- NOTE: If after 7 minutes, color on the saturation indicator has not appeared in the indicator window, proceed with the test below.
- Remove collection swab from mouth and insert it sponge first into the screening device, screw until the locking flange locks in place in the bottom of the device.
- Test device upright on flat surface and keep upright while test is running. Wait for the colored bands to appear in test results area. Read results at 10 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

- **INTERPRETATION OF DOA 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. The Oral Screen Saliva Drug Test is for professional in vitro diagnostic 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 The Oral Screen Saliva Drug Test. 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	11	19	14	16	12	18
+25% Cut-off	30	2	28	8	22	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	MOR		MTD		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	28	2	30	0	28	2	28	2
Cut-off	30	10	20	10	20	10	20	11	19
+25% Cut-off	30	9	21	2	28	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

Drug Conc. (Cut-off range)	n	MDMA		6-MAM		MOR25	
		-	+	-	+	-	+
0% Cut-off	30	30	0	30	0	30	0
-50% Cut-off	30	30	0	30	0	30	0
-25% Cut-off	30	25	5	30	0	26	4
Cut-off	30	14	16	15	15	13	17
+25% Cut-off	30	4	26	2	28	9	21
+50% Cut-off	30	0	30	0	30	0	30

B. Specificity

The following table lists the concentrations of compounds (in ng/ml) above which The Oral Screen Saliva Drug Test identified positive results at 10 minutes.

Amphetamine-Related Compounds	
D-Amphetamine	50
L-Amphetamine	4000
(+)-3,4-Methylenedioxyamphetamine	150
Phentermine	40000
PMA	125
Tyramine	3000
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-β-D-Glucuronide	5
Norbuprenorphine	10
Norbuprenorphine-3-β-D-Glucuronide	200
Cocaine-Related Compounds	
Cocaine	20
Benzoylecgonine	200
Ecgonine	100000
Ecgonine methyl ester	10000
Cotinine-Related Compounds	
Cotinine	50
Buprenorphine	>100000
EDDP -Related Compounds	
EDDP	20
Meperidine	20000
Methadone	20000
Norfentanyl	20000
Phencyclidine	20000
Promazine	10000
Promethazine	5000
Prothipendyl	10000
Prozine	2500
Ketamine-Related Compounds	
Ketamine(KET)	50
Norketamine	50
Dextromethorphan	25
Dextrorphan tartrate	25
D-Norpropoxyphene	1560

Ecstasy-Related Compounds	
3,4-Methylenedioxymethamphetamine	50
3,4-Methylenedioxyamphetamine	250
3,4-Methylenedioxyethylamphetamine	60
Paramethoxyamphetamine	1600
Paramethoxymethamphetamine	160
Methamphetamine-Related Compounds	
D-Methamphetamine	50
Fenfluramine	3000
L-Methamphetamine	500
L-Phenylephrine	2500
MDEA	400
3,4-Methylenedioxymethamphetamine	75
Mephentermine	200
PMMA	50
Procaine	2500
Opiates -Related Compounds	
Morphine	40
Codeine	10
Diacetylmorphine (Heroin)	50
Ethylmorphine	24
Hydrocodone	50
Hydromorphone	100
6-Monoacetylmorphine (6-MAM)	25
Morphine-3- β-d-glucuronide	50
Nalorphine	10000
Oxycodone	25000
Oxymorphone	25000
Thebaine	5000
Opiates -Related Compounds	
Morphine	25
Codeine	8
Diacetylmorphine (Heroin)	30
Ethylmorphine	15
Hydrocodone	25
Hydromorphone	80
6-Monoacetylmorphine (6-MAM)	15
Morphine-3- β-d-glucuronide	40
Nalorphine	10000
Oxycodone	25000
Oxymorphone	25000
Thebaine	5000
Oxycodone-Related Compounds	
Oxycodone	40
Hydrocodone	1000
Hydromorphone	6250
Naloxone	6250
Oxymorphone	1000
Phencyclidine-Related Compounds	
Phencyclidine (PCP)	10
Hydrocodone	2000
Hydromorphone	2000
Morphine-3- β-d-glucuronide	20000
Nalorphine	10000
Propoxyphene -Related Compounds	
Propoxyphene (PPX)	50
D-Norpropoxyphene	200

Meperidine	750
Mephentermine hemisulfate salt	1000
D-Methamphetamine	750
3,4-Methylenedioxyethylamphetamine	1500
Nordoxepin hydrochloride	1500
Phencyclidine	250
Promazine	400
Promethazine	1250
Marijuana -Related Compounds	
11-nor-Δ9 -THC-9 COOH	12
Δ8-Tetrahydrocannabinol	2000
Δ9-Tetrahydrocannabinol	4000
11-hydroxy-Δ9 -THC	300
Marijuana -Related Compounds	
Δ9-Tetrahydrocannabinol	50
Δ8-Tetrahydrocannabinol	75
11-nor-Δ9 -THC-9 COOH	12
11-hydroxy-Δ9 -THC	300
Cannabinol	2000
Cannabidiol	>10000
Methadone -Related Compounds	
Methadone	30
Alpha-Methadol	125
Biperiden	80000
Doxylamine	12500
2-Ethylidene-1,5-dimethyl-3,3-diphenyl pyrolidine (EDDP)	10000
Phencyclidine	12500
Pheniramine	25000

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
6-MAM-Related Compounds	
6-Monoacetylmorphine	25
Acetylcodeine	80
Buprenorphine	>10000
Codeine	15
Diacetylmorphine	15
Dihydrocodeine	50
Ethylmorphine	15
Hydrocodone	600
Hydromorphone	600
Morphine	20
Morphine-3-glucuronide	100
Nalorphine	1200
Thebaine	>20000

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 Oral Screen Saliva Drug Test when tested at concentrations up to 100 ug/ml.

Acetaminophen
Acetone
Acetophenetidine
Aspirin
Albumine
Atropine
Alphenal
α-hydroxyalprazolam
Alprazolam
Amantadine
Amikacin
Aminopyrine
Amitriptyline
Atenolol
Amoxicilline
Ampicilline
Apomorphine
Aspartame
Baclofen
Benzocaine
Bilirubin
Butethal
Carbamazepine
Cephalexin
Creatinine
Creatine
Chloramphenicol
Chloroquine
(±)-Epinephrine
Fentanyl
Dexamethasone
Diclofenac
Dicumarol
Diflunisal
Doxepin
D-Propoxyphene
DL-Tyrosine
Dopamine
DL-Tryptophan
Erythromycine
Estron 3 sulfate
Ethanol
Etodolac
(+)-Ephedrine
(-)-Ephedrine
Flupentixol
Fluoxetine
Furosemide
Gastrozepin
Gentamicin
Gentisic acid
Guaiacol Glyceryl Ether
Glucose
Haloperidol
Hemoglobin
Hexobarbital
N-Methylephedrine
(±)-Phenylpropanolamine
β-Phenylethylamine
(+)-Naproxen
Nifedipine
Nimesulide
Norchlordiazepoxide
Nordoxepinhydrochloride
(±)-Norketamine
Nortriptyline
Olanzapine
Opipramol
Oxalic acid
Oxymetazoline
Paroxetine
Pemoline
Pennicilline G
Perphenazine
Phenothiazine
Phenytoin
Prednisolone
Prednisone
Protriptyline
Quetiapine
Quinidine
Ranitidine
Rifampicine
Risperidone
Chlorpheniramine
Chlorprothixene
Cholesterol
Chorptothixene
Cimetidine
Ciprofloxacin
Citalopram
Clindamycin
Clobazam
Clomipramine
Clonidine
Clozapine
Caffeine
Cyclobenzaprine
Delorazepam
Desipramine
DL-Propanolol
Digoxin
(+)-cis-Diltiazem
Dimenhydrinate
4-Dimethylaminoantipyrine
Diphenhydramine
Hydralazine
Hydrochlorothiazide
Hydrocortisone
Ibuprofen
Imipramine
Indomethacin
Insulin
(-)Isoproterenol
Kanamycin
Ketoprofen
L-Thyroxine
Lincomycin
Loperamide
Lidocaine
Lindane
Lormetazepam
Metoprolol
Maprotiline
Metronidazole
Midazolam
Mirtazapin
Metoclopramide
Salbutamol
Salicylic acid
Sertraline
Sodium chloride
Spironolactone
Sulfamethoxazole
Sulindac
Theophylline
Thiamine
Thioridazine
Tobramycin
Triazolam
Triamterene
Trimethoprim
Trimipramine
Valproic acid
Vancomycin
Venlafaxine
Verapamil
Zolpidem

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GLOSSARY OF SYMBOLS

ρ	Catalog number	ϐ	Temperature limitation
ι	Consult instructions for use	Λ	Batch code
I	*In vitro* diagnostic medical device	ε	Use by
μ	Manufacturer	σ	Do not reuse

Eff. Date: 2016-03-31

DN: 1155164105

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

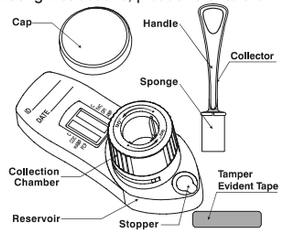
Materials Required but not Provided

- 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.



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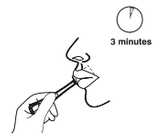

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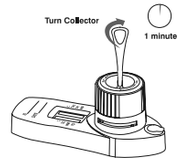

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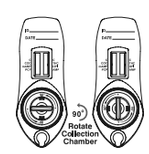

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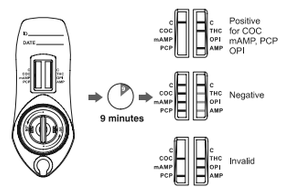

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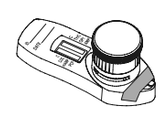

Step 8

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	

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Test	Calibrator	Cut-off
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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

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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

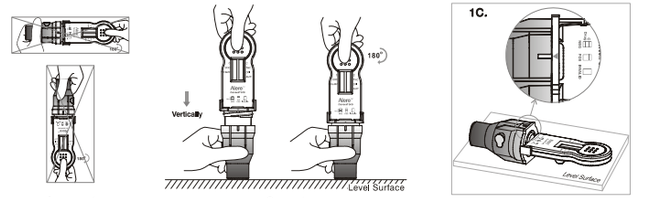
- Timer

DIRECTIONS FOR USE

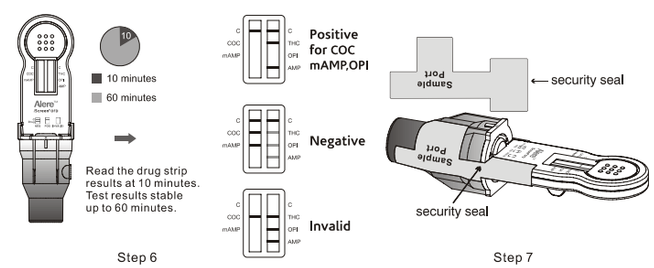
Allow the Alere *i*Screen® OFD Drug Test Device to come to room temperature [15-30°C (59-86°F)] prior to testing. Instruct the donor not to place anything in the mouth including food, drink, gum, or tobacco products for at least 10 minutes prior to collection.

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

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Alere™

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For Forensic Use Only
One Step Ethyl Glucuronide (EtG)
Test Dip Card
Package Insert

Package insert for testing of any combination of the following drugs: Ethyl Glucuronide

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

For forensic use only.

INTENDED USE & SUMMARY

Urine based tests for multiple drugs of abuse range from simple immunoassay tests to complex analytical procedures. The speed and sensitivity of immunoassays have made them the most widely accepted method to screen urine for multiple drugs of abuse.

The **One Step Ethyl Glucuronide (EtG) Test Dip Card** is a lateral flow chromatographic immunoassay for the qualitative detection of multiple drugs and drug metabolites in urine at the following cut-off concentrations in urine:[1]

Test	Calibrator	Cut-off (ng/mL)
Ethyl Glucuronide (EtG)	Ethyl Glucuronide	500

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/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

Ethyl Glucuronide (EtG) is a direct metabolite of ethanol alcohol. The presence of EtG in the urine can be used to detect recent alcohol consumption, even after the ethanol alcohol is no longer measurable. Consequently, the presence of EtG in the urine is a definitive indicator that alcohol has been ingested. Traditional laboratory practices typically measure the amount of alcohol present in the body.Depending on the amount of alcohol that has been consumed, this method usually reveals alcohol ingestion within the past few hours.

The presence of EtG in the urine, on the other hand, demonstrates that ethanol alcohol was ingested within the past three or four days, or roughly 80 hours after the ethanol alcohol has been metabolized by the body.As a result, it can be determined that a urine alcohol test employing EtG is a more accurate indicator of the recent consumption of alcohol as opposed to simply measuring for the existence of ethanol alcohol.

The **One Step Ethyl Glucuronide (EtG) Test Dip Card** yields a positive result when the Ethyl Glucuronide in urine exceeds 500ng/mL.

REAGENTS

Each test in the Test Strip contains mouse monoclonal antibody-coupled particles and corresponding drug-protein conjugates. A goat antibody is employed in each control line.

PRECAUTIONS

- For forensic use only.
- Do not use after the expiration date.
- The Test Strip 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 Strip 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 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

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 supernatant 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.

MATERIALS

Materials Provided

- Test panels
- Package insert

Materials Required But Not Provided

- Specimen collection container
- Timer

DIRECTIONS FOR USE

Allow the test device, and urine specimen to come to room temperature [15-30°C (59-86°F)] prior to testing.

1) Remove the test device from the foil pouch.

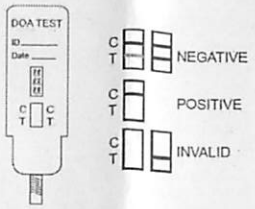
2) Remove the cap from the test device. Label the device with patient or control identifications.

3) Immerse the absorbent tip into the urine sample for 10-15 seconds. Urine sample should not touch the plastic device.

4) Replace the cap over the absorbent tip and lay the device flatly on a non-absorptive clean surface.

5) Read results at 5 minutes.

DO NOT INTERPRET RESULT AFTER 5 MINUTES.



INTERPRETATION OF RESULTS

(Please refer to the illustration above)

NEGATIVE:* Two lines appear. One red line should be in the control region (C), and another apparent red or pink line adjacent should be in the test region (Drug/T). This negative result indicates that the drug concentration is below the detectable level.

*NOTE: The shade of red in the test line region (Drug/T) will vary, but it should be considered negative whenever there is even a faint pink line.

POSITIVE: One red 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 your manufacturer.

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.

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 Ethyl Glucuronide (EtG) Test Dip Card** 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.
2. There is a possibility 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 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. The test does not distinguish between drugs of abuse and certain medications.
7. A positive result might be obtained from certain foods or food supplements.

PERFORMANCE CHARACTERISTICS

Reproducibility

Reproducibility studies were carried out using commercially available stork solutions of the drug analytes listed. Dilutions were made from the stork solution of each drug to the concentrations specified in the following tables. The results are listed in the following tables.

Ethyl Glucuronide (EtG)

Ethyl Glucuronide conc.(ng/mL)	Total number of Determinations	Result	Precision
Drug-free Urine	40	40 negative	>99%
250	40	40 negative	>99%
750	40	40 positive	>99%
1,000	40	40 positive	>99%

Analytical Sensitivity

A drug-free urine pool was spiked with drugs to the concentrations at ± 50% cut-off and ± 25% cut-off. The results are summarized below.

Drug Conc. (Cut-off range)	n	EtG	
		-	+
0% Cut-off	90	90	0
-50% Cut-off	90	90	0
-25% Cut-off	90	85	5
Cut-off	90	44	46
+25% Cut-off	90	3	87
+50% Cut-off	90	0	90
2X Cut-off	90	0	90

Analytical Specificity

The following table lists the concentration of compounds (ng/mL) that were detected positive in urine by the One Step Ethyl Glucuronide (EtG) Test Dip Card at a read time of 5 minutes.

Drug	Concentration (ng/ml)
ETHYL GLUCURONIDE (EtG)	
Ethyl-β-D-glucuronide	500
Ethyl-β-D-glucuronide-D5	500

Effect of Urinary Specific Gravity

Fifteen (15) urine samples of normal, high, and low specific gravity ranges (1.005, 1.015, 1.030) were spiked with drugs at 50% below and 50% above cut-off levels respectively. The One Step Ethyl Glucuronide (EtG) Test Dip Card was tested in duplicate using ten 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 pH ranges of 4.0, 4.5, 5.0, 6.0 and 9.0, and spiked with drugs at 50% below and 50% above cut-off levels. The spiked, pH-adjusted urine was tested with The One Step Ethyl Glucuronide (EtG) Test Dip Card. 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 Ethyl Glucuronide, positive urine. The following compounds show no cross-reactivity when tested with the One Step Ethyl Glucuronide (EtG) Test Dip Card at a concentration of 100 µg/mL.

Non Cross-Reacting Compounds

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

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1.Hawks RL. Chiang CN, eds. Urine Testing for Drugs of Abuse Rockville: Department of Healtb and Human Services, National Institute on Drug Abuse;1986

2.Substance Abuse and Mental Health Services Administration. Mandatory Guidelines for Federal Workplace Drug Testing Programs. 53 Federal Register, 1988

3.McBay AJ. Drug-analysis technology-pitfails and problems of drug testing. Clin Chem 1987 Oct: 33 (11 Suppl): 33B-40B

4.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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B20853-01

One Step Synthetic Cannabinoids Drug Screen Test

FOR FORENSIC USE ONLY

INTENDED USE

The One Step Synthetic Cannabinoids Drug Screen Test is a lateral flow immunoassay for the specific, qualitative detection of synthetic cannabinoids metabolites in human urine at a cut-off level of 30ng/mL. The synthetic cannabinoids detected by the test include, but are not limited to, the metabolites of JWH-018 and JWH-073. This assay is intended for forensic use only.

This assay provides only a preliminary result. Careful 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. Liquid Chromatography/Mass Spectrometry (LC/MS) is the preferred confirmation method.

SUMMARY AND EXPLANATION

Synthetic Cannabis is a family of compounds that when consumed mimics the effects of Marijuana. It is also known by the brand names of K2 and Spice, both of which have largely become trademarks used to refer to any synthetic cannabinoids product. Studies suggest that synthetic cannabinoid intoxication is associated with acute psychosis, and the worsening of previously stable psychotic disorders among vulnerable individuals such as those with a family history of mental illness. JWH-018 and JWH-073 are the primary synthetic cannabinoid receptor agonists responsible for the euphoric and psychoactive effects that imitate Marijuana and are among the numerous compounds found in "herbal" incense or smoke blends. Most popular herbal smoking products are marketed under the brand names of K-2, K-3, Spice, Genie, Black Mombo, Pot-pouri, Buzz, Pulse, Hush, Mystery, Earthquake, Ocean Blue, Stinger, Yucatan Fire, as well as many others.

TEST PRINCIPLE

The One Step Synthetic Cannabinoids Drug Screen Test 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 migrates upward and rehydrates 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. 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 the test line on the test region indicates a preliminary **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 test line and control line, and a **positive** urine sample will generate only control line. The presence of control line serves as a built-in control, which demonstrates that the test is performed properly.

REAGENTS & MATERIALS SUPPLIED

- 25 individually wrapped test cards. Each card consists of a test strip in a plastic test strip holder. The test strip contains a colloidal gold pad containing coated drug-targeted antibody and rabbit antibody. It also contains a membrane coated with drug- protein conjugate in the test band and goat anti-rabbit antibody in the control band region.
- One instruction sheet
- Security seals (if applicable)

MATERIAL REQUIRED BUT NOT PROVIDED

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

WARNINGS AND PRECAUTIONS

- For Forensic Use Only
- Urine specimens and used cards may be potentially infectious. Proper handling and disposal methods should be established.
- This is a single use test.
- Avoid cross-contamination of urine samples by using a new specimen collection container for each urine sample.
- The test card should remain sealed in the foil pouch until ready for use.
- Do not use the test kit after the expiration date.

STORAGE

The One Step Synthetic Cannabinoids Drug Screen Test 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.

SPECIMEN COLLECTION AND HANDLING

Fresh urine does not require any special handling or pretreatment. A clean, dry plastic or glass container may be used for specimen collection. If the specimen will not be tested immediately after the collection, the specimen may be refrigerated at 2-8°C up to 3 days or frozen at -20°C for longer a 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.

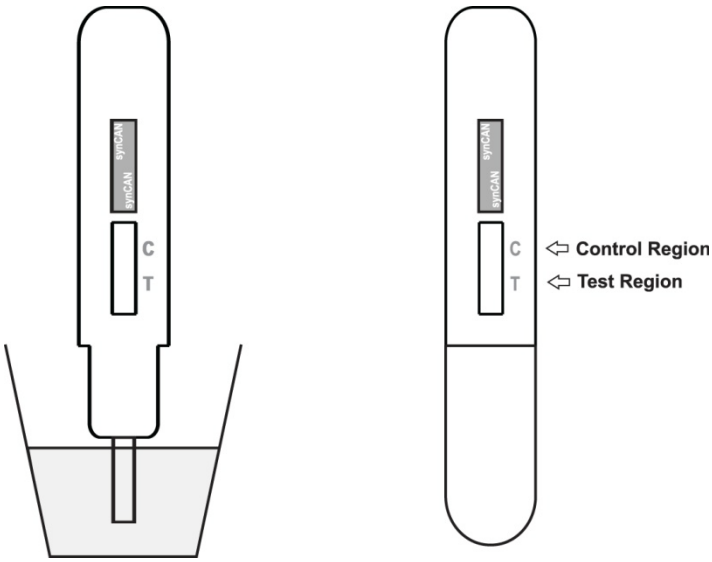
ASSAY PROCEDURE FOR DRUG TEST

Preparation

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

Testing

1. Remove the card test from the sealed pouch. Write donor name or ID on the plastic. Remove the cap to expose the sampling tips.
2. Immerse the sampling tip into the urine specimen for approximately 15 to 30 seconds. Do not allow specimen to come in contact with the plastic housing. Replace the cap over the sampling tip and then place the test card on a flat surface.
3. Read results of drugs of abuse tests in 5 minutes. Do not interpret result after 60 minutes. Refer to interpretation of results section.



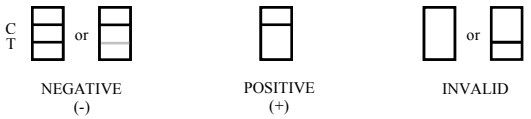
Drug screen card test

INTERPRETATION OF RESULTS

Negative (-): A colored line appears at the control region (C) and a colored line appears at a specific drug test region (T). The appearance of a control line and test line indicates a negative test result. The test lines may have varying intensity either weaker or stronger in color than that of the control line.

Positive (+): A colored line appears in the control region and no colored line appears at a specific drug test region. The complete absence of a test line indicates a preliminary positive result for that particular drug. A preliminary positive result for a drug indicates that the concentration of that drug in the 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

QUALITY CONTROL

An internal procedural control is included in the test card. 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 One Step Synthetic Cannabinoids Drug Screen Test cards 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 the test indicates only the presence of a drug/metabolite and does not indicate or measure intoxication.
- There is a possibility that technical or procedural errors as well as other substances present in the urine sample may interfere with the test and cause false results. See SPECIFICITY and INTERFERENCE for lists of substances that will produce positive results and those that do not interfere with test performance.
- If adulteration is suspected, the test should be repeated with a new sample.

PERFORMANCE CHARACTERISTICS

A. Accuracy

The accuracy of the One Step Synthetic Cannabinoids Drug Screen Test was evaluated in comparison to liquid chromatography/tandem mass spectrometry (LC/MS-MS). Eighty-seven (87) specimens, comprised of 43 negative urine samples and 44 positive urine samples, were blinded and tested with the One Step Synthetic Cannabinoids Drug Screen Test and compared to the LC/MS-MS results. The testing showed a >95% agreement between the two methods.

B. Precision

A study was conducted in an effort to determine the precision of the One Step Synthetic Cannabinoids Drug Screen Test. Testing was conducted using three different lots of product to demonstrate the within-run and between-run precision. The correlation with expected results for the solutions targeted to +/-50% of the cutoff was > 99% across all lots.

C. Specificity

The specificity for the One Step Synthetic Cannabinoids Drug Screen Test was determined by evaluating the performance of assay when tested with 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)
JWH-018 Pentanoic acid	30	JWH-073 Butanoic acid	15
JWH-018-N-4-hydroxypentyl	200	JWH-073-N-4- hydroxybutyl	300
JWH-081-N-5- hydroxypentyl	1000	JWH-200-N-6-hydroxyindole	300
AM-2201-N-4-hydroxypentyl	1000	JWH-250-N-5-hydroxyindole	300
RCS-4-N-5- Carboxypentyl	250		

D. INTERFERENCE

The following compounds were evaluated for potential positive and/or negative interference with the One Step Synthetic Cannabinoids Drug Screen Test. All compounds were dissolved in a Drug-free control solutions and tested with One Step Synthetic Cannabinoids Drug Screen Test. 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
Acetylsalicylic acid
Albumin
Amitriptyline
Amobarbital
Amphetamine
Ampicillin
Ascorbic Acid
Atropine Sulfate
Benzocaine
Benzoylecgonine HCL
Bilirubin
Bup-3-B-glucuronide
Buprenorphine
Butalbital
Caffeine
Cannabidiol
Cannabinol
Chloroquine
(+)-Chlorpheniramine
(+/-)-Chlorpheniramine
+/- CP 47,497
Cocaine
Codeine
Cotinine
Creatine
Delta-8-tetrahydrocannabinol
Dexbrompheniramine
Dextromethorphan
Dextrose
Diazepam
4-Dimethylaminoantipyrine
Diphenhydramine
Dopamine
Ecgonine HCL
Ecgonine Methyl Ester
EDDP
Efavirenz
Ephedrine
(+/-)-Epinephrine
Erythromycin
Ethanol
Furosemide
Glucose
Hemoglobin
Hippuric acid
Hydrocodone
Hydromorphone
HU-211
Ibuprofen
Immipraime
(+/-)-Isoproterenol
11-hydroxy-delta-9-THC
11-nor-Δ^9-THC-9-COOH
Ketamine
Lansoprazole
Lidocaine
MDA
MDMA
Methadone
Methamphetamine
Morphine Sulfate
Myoglobin
Nalophine
Niacinamide
Nicotine
Nortriptyline
Omeprazole
Oxalic Acid
Oxycodone
Oxymorphone
Oxazepam
Pantoprazole
Penicillin-G
Pentobarbital
Pheniramine
d-Propoxyphene
Phencyclidine
Phenylephrine
β-Phenylethylamine
Procaine
Pseudoephedrine
Quinidine
Ranitidine
Riboflavin
RSC-4-N-5-hydroxypentyl
Secobarbital
Sodium Chloride
Sulindac
Theophylline
Trimipramine
Tyramine
Urea

E. Effect of Specimen pH

Drug-free sample solutions were adjusted to pH 4-9 and tested using One Step Synthetic Cannabinoids Drug Screen Test. 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-free sample solutions were adjusted to specific gravity 1.000-1.030 and tested using One Step Synthetic Cannabinoids Drug Screen Test. 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.

BIBLIOGRAPHY OF SUGGESTED READING

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2. Drug Fact Sheet, DEA, January 2012, http://www.dea.gov.

Manufactured by:
Ameditech, Inc.
10340 Camino Santa Fe, Suite F
San Diego, CA 92121
(858)-535-1968 • Fax (858) 535-1838
42131-GED-sCAN Rev. Original

K122633

BRANAN BMC MEDICAL CORP

FEB 7 2013

5.0 510(k) Summary

510(k) SUMMARY

This summary of safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR 807.92(c).

Establishment Name and Address

Branan Medical Corporation
140 Technology Dr., Bldg. 400
Irvine, CA 92618
Tel: (949) 598-7166
Fax: (949) 598-7167

Contact Person: Olivia Chan
Tel: (949) 598-7166 ext. 113
Email: olivia@brananmedical.com

Date Prepared: August 24, 2012

Proprietary and Trade Name

ToxCup® Drug Screen Cup

Common Name

Qualitative Lateral Flow Immunoassay

Classification Panel

Toxicology (91)

Product Code and Regulation Number

Device	Panel	Product Code	Classification	Regulation Section	Description
THC	Toxicology (91)	LDJ	II	862.3870	Cannabinoid Test System
COC	Toxicology (91)	DIO	II	862.3250	Cocaine and Cocaine Metabolite Test System
OPI	Toxicology (91)	DJG	II	862.3650	Opiates Test System
MET	Toxicology (91)	DJC	II	862.3610	Methamphetamine Test System
AMP	Toxicology (91)	DKZ	II	862.3100	Amphetamine Test System
BZO	Toxicology (91)	JXM	II	862.3170	Benzodiazepine Test System, Over The Counter
BAR	Toxicology (91)	DIS	II	862.3150	Barbiturate Test System
MTD	Toxicology (91)	DJR	II	862.3620	Methadone Test System
BUPG	Toxicology (91)	DJG	II	862.3650	Opiates (Buprenorphine) Test System
TCA	Toxicology (91)	LFG	II	862.3910	Tricyclic Antidepressant Drugs Test System
MDMA	Toxicology (91)	DJC	II	862.3610	Methamphetamine (MDMA) Test System, Over The Counter
OXY	Toxicology (91)	DJG	II	862.3650	Opiates (Oxycodone) Test System, Over the Counter
PCP	Toxicology (91)	LCM	II	862.3100	Enzyme immunoassay Phencyclidine
PPX	Toxicology (91)	JXN	II	862.3700	Propoxyphene Test System

Device Classification

Class II

Substantially Equivalent Devices

K082898 – Amedica Home Drug Test Cup

Device Description

The ToxCup® Drug Screen Cup is based on the principle of highly specific immunochemical reactions between antigens and antibodies. It utilizes a competitive immunoassay procedure in which an immobilized drug conjugate competes with the drug present in urine for limited antibody binding sites. The ToxCup® Drug Screen Cup device consists of individual test strips, in single drug analyte cassette dip format and/or double analyte cassette dip format, assembled into separate chambers of a plastic insert and can detect up to 14 drugs in human urine at various cutoff concentrations. The presence of a color band at a specific test region indicates a negative result for that particular test. The absence of a color band at a specific test region indicates presumptive positive result for that particular test.

A control band at the control region should always appear regardless of the presence of the drug or its metabolites. The presence of the control band during testing serves as a built in control which indicates that the test has completed and is valid.

Intended Use

The ToxCup® Drug Screen Cup in single drug analyte cassette dip format and/or double analyte cassette dip format is an *in vitro* screening test for the rapid detection of multiple drugs and drug metabolites in human urine at or above the following cutoff concentration:

AMP	Amphetamine	500 ng/ml
BAR	Secobarbital	300 ng/ml
BUPG	Buprenorphine Glucuronide	10 ng/ml
BZO	Oxazepam	300 ng/ml
COC	Benzoylecgonine	150 ng/ml
MDMA	3,4-methylenedioxymethamphetamine	500 ng/ml
MET	Methamphetamine	500 ng/ml
MTD	Methadone	300 ng/ml
OPI	Morphine	300 ng/ml
OXY	Oxycodone	100 ng/ml
PCP	Phencyclidine	25 ng/ml
PPX	Propoxyphene	300 ng/ml
TCA	Nortipltyline	1000 ng/ml
THC	11-nor-Δ9-Tetrahydrocannabinol-9-carboxylic acid	50 ng/ml

Indications for Use

The ToxCup® Drug Screen Cup is an *in vitro* screening test for the rapid detection of multiple drugs and drug metabolites in human urine at or above the following cutoff concentration:

AMP	Amphetamine	500 ng/ml
BAR	Secobarbital	300 ng/ml
BUPG	Buprenorphine Glucuronide	10 ng/ml
BZO	Oxazepam	300 ng/ml
COC	Benzoylecgonine	150 ng/ml
MDMA	3,4-methylenedioxymethamphetamine	500 ng/ml
MET	Methamphetamine	500 ng/ml
MTD	Methadone	300 ng/ml
OPI	Morphine	300 ng/ml
OXY	Oxycodone	100 ng/ml
PCP	Phencyclidine	25 ng/ml
PPX	Propoxyphene	300 ng/ml
TCA	Nortriptyline	1000 ng/ml
THC	11-nor-Δ9-Tetrahydrocannabinol-9-carboxylic acid	50 ng/ml

These tests provide visual qualitative results and are intended for *in vitro* diagnostic use only. The ToxCup® Drug Screen Cup is available in single drug analyte cassette dip format and/or double drug analyte cassette dip format. It is intended for prescription point-of-care and over-the-counter consumer use.

These tests provide only a preliminary test result and are the first step in a two-step process for detecting drugs of abuse in urine. The second step is confirming the results in a certified laboratory. For a quantitative result or to confirm preliminary positive results obtained by the ToxCup® Drug Screen Cup, a more specific alternative method such as Gas Chromatography/Mass Spectrometry (GC/MS) must be used. Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly when a preliminary positive result is indicated.

Predicate Device Comparison

Similarities		
Feature	**Subject Devices** (ToxCup® Drug Screen Cup)	**Predicate Device** (Amedica Home Drug Test Cup)
Intended Use	Screening Device	Screening Device
Matrix	Human Urine	Human Urine
Test Principle	Competitive immunoassay	Competitive immunoassay
Analytes and Cut-Off	THC 50ng/ml Morphine 300ng/ml Phencyclidine 25ng/ml Secobarbital 300ng/ml Benzodiazepines 300ng/ml Methadone 300ng/ml Oxycodone 100ng/ml MDMA 500ng/ml Nortriptyline 1000ng/ml	THC 50ng/ml Morphine 300ng/ml Phencyclidine 25ng/ml Secobarbital 300ng/ml Benzodiazepines 300ng/ml Methadone 300ng/ml Oxycodone 100ng/ml MDMA 500ng/ml Nortriptyline 1000ng/ml
Housing	Plastic lid and cup base	Plastic lid and cup base
Internal Procedural Controls	Control line	Control line
Intended User	Over The Counter Consumer	Over The Counter Consumer
Testing Method	Lateral Flow Immunoassay	Lateral Flow Immunoassay

Differences		
Feature	**Subject Devices** (ToxCup® Drug Screen Cup)	**Predicate Device** (Amedica Home Use Drug Test Cup)
Test Strip	Test up to 14 drugs	Test up to 12 drugs
Analytes and Cut-Off	Benzoylecgonine 150ng/ml Amphetamine 500ng/ml Methamphetamine 500ng/ml Buprenorphine Glucuronide 10ng/ml Propoxyphene 300ng/ml	Benzoylecgonine 300ng/ml Amphetamine 1000ng/ml Methamphetamine 1000ng/ml
Method Comparison Total % agreement	≥ 95%	≥ 93%
Storage	Sealed pouch at 15-30°C	Sealed pouch at 2-30°C
Intended User	Over The Counter Consumer and Prescription Point-of-Care use	Over The Counter Consumer
Reading Time	5 – 8 minutes	4 - 5 minutes

Test Summary:

Performance Specifications

The performance characteristics of the ToxCup® Drug Screen Cup were based on evaluations by the following analytical performance studies:

- Stability
- Optimal Read Time
- Precision/reproducibility
- Method Comparison
- Specificity and Interference
- Consumer Study

Conclusion

The performance characteristics studies performed demonstrate substantial equivalency between the ToxCup® Drug Screen Cup, the predicate kit Amedica Home Drug Test Cup.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

February 7, 2013

Branan Medical Corporation
c/o Olivia Chan
140 Technology Dr, Suite 400
Irvine, CA 92618

Re: k122633
Trade/Device Name: ToxCup® Drug Screen Cup
Regulation Number: 21 CFR 862.3870
Regulation Name: Cannabinoid test system
Regulatory Class: II
Product Code: LDJ, DIO, DJG, DJC, DKZ, JXM, DIS, DJR, LFG, LCM, JXN
Dated: January 18, 2013
Received: January 22, 2013

Dear Ms. Chan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for

the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Carol C. Benson for

Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): k122633

Device Name: ToxCup® Drug Screen Cup

Indications for Use:

The ToxCup® Drug Screen Cup is an in vitro screening test for the rapid detection of multiple drugs and drug metabolites in human urine at or above the following cutoff concentration:

AMP	Amphetamine	500 ng/ml
BAR	Secobarbital	300 ng/ml
BUPG	Buprenorphine Glucuronide	10 ng/ml
BZO	Oxazepam	300 ng/ml
COC	Benzoylecgonine	150 ng/ml
MDMA	3,4-methylenedioxymethamphetamine	500 ng/ml
MET	Methamphetamine	500 ng/ml
MTD	Methadone	300 ng/ml
OPI	Morphine	300 ng/ml
OXY	Oxycodone	100 ng/ml
PCP	Phencyclidine	25 ng/ml
PPX	Propoxyphene	300 ng/ml
TCA	Nortriptyline	1000 ng/ml
THC	11-nor-Δ9-Tetrahydrocannabinol-9-carboxylic acid	50 ng/ml

These tests provide visual qualitative results and are intended for in vitro diagnostic use only. The ToxCup® Drug Screen Cup is available in double drug analyte cassette dip format. It is intended for prescription point-of-care use and over-the-counter consumer use.

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

Denise Johnson-Iyles -S
2013.02.05 15:21:38 -05'00'

Division Sign-Off
Office of In Vitro Diagnostics and Radiological Health

510(k) k122633

Indications for Use

510(k) Number (if known): k122633

Device Name: ToxCup® Drug Screen Cup

Indications for Use:

These tests provide only a preliminary test result and are the first step in a two-step process for detecting drugs of abuse in urine. The second step is confirming the results in a certified laboratory. For a quantitative result or to confirm preliminary positive results obtained by the ToxCup® Drug Screen Cup, a more specific alternative method such as Gas Chromatography/Mass Spectrometry (GC/MS) must be used. Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly when a preliminary positive result is indicated.

Prescription Use ___X___ (21 CFR Part 801 Subpart D)	And/Or	Over the Counter Use __X__. (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

Denise Johnson-lyles -S
2013.02.05 15:21:59 -05'00'

Division Sign-Off
Office of In Vitro Diagnostics and Radiological Health

510(k) ___k122633_____

NOV 13 2006

510(k) SUMMARY

This summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The Assigned 510(k) number is K061718.

Submitter:

INNOVACON Laboratories, Inc.
4106 Sorrento Valley Boulevard
San Diego, California 92121

Tel.: 858-535-2030
Fax: 858-535-2038

Date:

June 16, 2006

Contact Person:

Edward Tung, Ph.D.

Product Names:

Innovacon® Spectrum II Test Card
Innovacon® Spectrum II Test Card with Integrated Cups (Innovacon 014 Cup or E-Z Action Multi-Drug Test Cup and Innovacon 022 Cup or E-Z Start Multi-Drug Test Cup)

Common Name:

Multi-drug Multi-line lateral flow immunochromatographic test for the simultaneous and qualitative detection of Amphetamine, Cocaine, Marijuana, Benzodiazepines, Tricyclic Antidepressants, Barbiturates, Morphine, Phencyclidine, Oxycodone, Propoxyphene, Methadone, Opiate, Methamphetamine, Buprenorphine and Methylenedioxymethamphetamine in urine.

Regulation Name:

Amphetamine, Cocaine, Marijuana, Benzodiazepines, Tricyclic Antidepressants, Barbiturates, Morphine, Phencyclidine, Oxycodone, Propoxyphene, Methadone, Opiate, Methylenedioxymethamphetamine, Buprenorphine and Methamphetamine test systems.

Product Code:

LDJ, DIO, DJC, DKZ, DJG, LCM, JXM, DJR, DIS, LFG, LAF, JXN

Classification Number:

21 CFR § 862.3870, 21 CFR § 862.3250, 21 CFR § 862.3610, 21 CFR § 862.3100,
21 CFR § 862.3650, 21 CFR § 862.3170, 21 CFR § 862.3620, 21 CFR § 862.3150,
21 CFR § 862.3910, 21 CFR § 862.3700

Device Classification:

The Amphetamine, Cocaine, Marijuana, Benzodiazepines, Tricyclic Antidepressants, Barbiturates, Morphine, Phencyclidine, Oxycodone, Propoxyphene, Methadone, Opiate, Methylenedioxymethamphetamine, Buprenorphine and Methamphetamine test systems have been classified as Class II devices with moderate complexity.

The Innovacon Spectrum II Test Card and Innovacon Spectrum II Test Card with Integrated Cups (Innovacon 014 Cup or E-Z Action Multi-Drug Test Cup and Innovacon 022 Cup or E-Z Start Multi-Drug Test Cup) are similar to other FDA-cleared devices for the qualitative and simultaneous detection of Amphetamine, Cocaine, Marijuana, Benzodiazepines, Tricyclic Antidepressants, Barbiturates, Morphine, Phencyclidine, Oxycodone, Propoxyphene, Methadone, Opiate, Methylenedioxymethamphetamine, Buprenorphine and Methamphetamine in human urine.

Intended Use:

The Innovacon Spectrum II Test Card and Innovacon Spectrum II Test Card with Integrated Cups (Innovacon 014 Cup or E-Z Action Multi-Drug Test Cup and Innovacon 022 Cup or E-Z Start Multi-Drug Test Cup) are rapid chromatographic immunoassays for the qualitative and simultaneous detection of Marijuana, Cocaine, Methylenedioxymethamphetamine, Amphetamine, Morphine, Opiates, Methadone, Methamphetamine, Phencyclidine,

Benzodiazepine, Oxycodone, Propoxyphene, Tricyclic Antidepressants, Buprenorphine and Barbiturate in human urine at the cutoff concentrations of:

1,000 ng/mL or 300 ng/mL for Amphetamine,
300 ng/mL for Barbiturate,
300 ng/mL for Benzodiazepines,
300 ng/mL or 150 ng/mL for Cocaine,
50 ng/mL for Marijuana,
300 ng/mL for Methadone,
500 ng/mL or 1,000 ng/mL for Methamphetamine,
500 ng/mL for Methylenedioxymethamphetamine,
300 ng/mL for Morphine,
2,000 ng/mL for Opiates,
100 ng/mL for Oxycodone,
25 ng/mL for Phencyclidine,
300 ng/mL for Propoxyphene,
10 ng/mL for Buprenorphine, and
1,000 ng/mL for Tricyclic Antidepressants.

Configurations of the Innovacon Spectrum II Test Card and Innovacon Spectrum II Test Card with with Integrated Cups (Innovacon 014 Cup or E-Z Action Multi-Drug Test Cup and Innovacon 022 Cup or E-Z Start Multi-Drug Test Cup) can consist of any combination of the above listed drug analytes. They are intended for healthcare professionals including professionals at point-of-care sites.

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) are the preferred confirmatory methods. Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are used.

Description:

The Innovacon Spectrum II Test Card and Innovacon Spectrum II Test Card with with Integrated Cups (Innovacon 014 Cup or E-Z Action Multi-Drug Test Cup and Innovacon 022 Cup or E-Z Start Multi-Drug Test Cup) are competitive binding, lateral flow immunochromatographic assays for the qualitative and simultaneous detection of Marijuana, Cocaine, Methylenedioxymethamphetamine, Amphetamine, Morphine, Opiates, Methadone, Methamphetamine, Phencyclidine, Benzodiazepine, Oxycodone, Propoxyphene, Tricyclic Antidepressants, Buprenorphine and Barbiturate in human urine at the cutoff concentrations of:

1,000 ng/mL or 300 ng/mL for Amphetamine,
300 ng/mL for Barbiturate,
300 ng/mL for Benzodiazepines,
300 ng/mL or 150 ng/mL for Cocaine,
50 ng/mL for Marijuana,
300 ng/mL for Methadone,
500 ng/mL or 1,000 ng/mL for Methamphetamine,
500 ng/mL for Methylenedioxymethamphetamine,
300 ng/mL for Morphine,
2,000 ng/mL for Opiates,
100 ng/mL for Oxycodone,
25 ng/mL for Phencyclidine,
300 ng/mL for Propoxyphene,
10 ng/mL for Buprenorphine, and
1,000 ng/mL for Tricyclic Antidepressants.

These tests can be performed without the use of an instrument.

A positive urine specimen will not generate a colored-line for the specific drug tested in the designated test region. A negative urine specimen or a urine specimen containing of Marijuana, Cocaine, Methylenedioxymethamphetamine, Amphetamine, Morphine, Opiates, Methadone, Methamphetamine, Phencyclidine, Benzodiazepine, Oxycodone, Propoxyphene, Tricyclic Antidepressants, Buprenorphine and Barbiturate at the concentrations below the designated cutoff levels will generate a colored line in the designated test region for the drug. To serve as a procedural control, a color line will always appear at the control region, indicating that proper volume of specimen has been added and membrane wicking has occurred.

Unmodified ACON Devices:

The Innovacon® Spectrum II Test Card and Innovacon Spectrum II Test Card with with Integrated Cups (Innovacon 014 Cup or E-Z Action Multi-Drug Test Cup and Innovacon 022 Cup or E-Z Start Multi-Drug Test Cup) are a "modified" product format derived from the previously FDA-cleared ACON Spectrum Multi-drug Multi-line Drug Screen Test Card and 6 ACON Single DOA Tests. These seven legally marketed but unmodified devices and their 510(k) numbers under which they were previously cleared are listed in Table 1.

Table 1. Unmodified ACON Devices with K Numbers and Product Codes.

Previously Cleared ACON Drug of Abuse Test	510(k) Number	Product Code
ACON Spectrum Multi-Drug Multi-Line Drug Screen Test Card and Test Card with Integrated Split E-Z Key Cup	K031759	LDJ DIO DKZ DJG LCM JXM DJR DIS LFG
ACON COC-150 One Step Cocaine Test Strip/Test Device	K032903	DIO
ACON mAMP-500 One Step Methamphetamine Test Strip/Test Device	K033299	LAF
ACON PPX One Step Propoxyphene Test Strip/Test Device	K040445	JXN
ACON AMP 300 One Step Amphetamine Test Strip/Test Device	K041822	DKZ
ACON OXY II One Step Oxycodone Test Strip/Test Device	K043507	DJG
ACON BUP One Step Buprenorphine Test Strip/Test Device	K060466	DJG

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

NOV 13 2006

Edward Tung, Ph.D.
INNOVACON Laboratories, Inc.
4106 Sorrento Valley Boulevard
San Diego, California 92121

Re: k061718
Trade/Device Name: Innovacon Spectrum II Test Card
Innovacon Spectrum II Test Card with Integrated Cups (Innovacon 014 Cup or E-Z Action Multi-Drug Test Cup and Innovacon 022 Cup or E-Z Start Multi-Drug Test Cup)
Regulation Number: 21 CFR 862.3100
Regulation Name: Amphetamine test system
Regulatory Class: Class II
Product Code: DKZ, DIS, JXM, LDJ, DIO, DJR, DJC, DJG, LFG, LCM, JXN
Dated: October 20, 2006
Received: October 23, 2006

Dear Dr. Tung:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0484. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Alberto Gutierrez, Ph.D.
Director
Division of Chemistry and Toxicology
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

10. INDICATIONS FOR USE

510(k) Number (if known):

Device Name: Innovacon Spectrum II Test Card
Innovacon Spectrum II Test Card with Integrated Cups (Innovacon 014 Cup or E-Z Action Multi-Drug Test Cup and Innovacon 022 Cup or E-Z Start Multi-Drug Test Cup)

Indications for Use:

The Innovacon Spectrum II Test Card and Innovacon Spectrum II Test Card with Integrated Cups (Innovacon 014 Cup or E-Z Action Multi-Drug Test Cup and Innovacon 022 Cup or E-Z Start Multi-Drug Test Cup) are rapid chromatographic immunoassays for the qualitative and simultaneous detection of Marijuana, Cocaine, Methylenedioxymethamphetamine, Amphetamine, Morphine, Opiates, Methadone, Methamphetamine, Phencyclidine, Benzodiazepine, Oxycodone, Propoxyphene, Tricyclic Antidepressants, Buprenorphine and Barbiturate in human urine at the cutoff concentrations of:

1,000 ng/mL or 300 ng/mL for Amphetamine,
300 ng/mL for Barbiturate,
300 ng/mL for Benzodiazepines,
300 ng/mL or 150 ng/mL for Cocaine,
50 ng/mL for Marijuana,
300 ng/mL for Methadone,
500 ng/mL or 1,000 ng/mL for Methamphetamine,
500 ng/mL for Methylenedioxymethamphetamine,
300 ng/mL for Morphine,
2,000 ng/mL for Opiates,
100 ng/mL for Oxycodone,
25 ng/mL for Phencyclidine,
300 ng/mL for Propoxyphene,
10 ng/mL for Buprenorphine, and
1,000 ng/mL for Tricyclic Antidepressants.

Configurations of the Innovacon Spectrum II Test Card and Innovacon Spectrum II Test Card with Integarted Cups (Innovacon 014 Cup or E-Z Action Multi-Drug Test Cup and Innovacon 022 Cup or E-Z Start Multi-Drug Test Cup) can consist of any combination of the above listed drug analytes. They are intended for healthcare professionals including professionals at point-of-care sites.

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) are the preferred confirmatory methods. Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are used.

Prescription Use ... X ... (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use (21 CFR 807 Subpart C) _____

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Carol Benson
Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

K061718