State of West Virginia
Department of Administration
Purchasing Division
2019 Washington Street East
Post Office Box 50130
Charleston, WV 25305-0130

Solicitation

NUMBER	PAGE
DJS010355	1

ADDRESS CORRESPONDENCE TO ATTENTION OF:
TARA LYLE
304-558-2544

VENDOR
RFQ COPY
TYPE NAME/ADDRESS HERE
PREMIER BIOTECH, INC
PO BOX 296
EXCELSIOR, MN 55331

SHIP TO
DIVISION OF JUVENILE SERVICES

VARIOUS LOCALES AS
INDICATED BY ORDER

DATE PRINTED
08/01/2012

BID OPENING DATE: 08/14/2012 BID OPENING TIME 1:30PM

LINE	QUANTITY	UOP	CAT. NO.	ITEM NUMBER	UNIT PRICE	AMOUNT
				ADDENDUM NO. 4		
	SEE ATTACHED PAGES.					
				END OF ADDENDUM NO. 4		
0001	1	LS		961-48		
	DRUG TESTING SERVICES					
	****** THIS IS THE END OF RFQ DJS010355 ****** TOTAL:					

SEE ATTACHED BID SHEET FOR PRICING

RECEIVED
2012 AUG 14 AM 9:23
WV PURCHASING DIVISION

SIGNATURE Carrie Spriggs TELEPHONE 888-686-9909 DATE 8/14/12

TITLE CUST SVC SUPER FEIN 27-0962878 ADDRESS CHANGES TO BE NOTED ABOVE

WHEN RESPONDING TO SOLICITATION, INSERT NAME AND ADDRESS IN SPACE ABOVE LABELED 'VENDOR'

ADDENDUM ACKNOWLEDGEMENT FORM
SOLICITATION NO.: DJS010355

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 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.

PREMIER BIOTECH
Company

Annie Sprague
Authorized Signature

8/13/17
Date

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

	DJS010355 - Drug Testing Services			
	Bid Form - Revised 8/1/12			
Item #	Description	Yearly Estimated Quantity	Unit Price	Extended Amount
1	11 panel(C) Urine CUP	3500	$3.81	$13,335.00
2	11 panel(C) Oral 10PANEL W/UR INSTP	1500	$9.95	$14,925.00
3	6 panel Oral Synthetic W/KRON SIDE	500	$10.50	$5,250.00
4	6 panel Urine Synthetic CUP	500	$6.45	$3,225.00
5	Confirmation for 6 panel Oral	50	N/A	0
6	Confirmation for 6 panel Urine	50	N/A	0
7	Onsite Training per the specifications	1	N/A	0
8	MRO or Lab Rep as Expert Witness	5	N/A	0
	Failure to use this form may result in disqualification		**GRAND TOTAL:**	$36,735.00
	Bidder / Vendor Information: 433104501			
	Name: PREMIER BIOTECH			
	Address: PO BOX 296			
	EXCELSIOR, MN 55331			
	Phone and Fax Nos.: 888-686-9909 888-600-1189			
	Email Address: csprague@premierbiotech.com			
	Authorized Signature: Connie Sprague			

Premier Biotech, Inc Bid Response
Vendor number: 423104501
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ADDITIONAL PRICING OFFERED

Premier Biotech has the ability to provide to DJS either an 11 panel on-site dip test as well as an 11 panel an on-site 11 panel all inclusive cup. DJS had also stated in the questions and answers that they were looking for a 4 panel and 6 panels drug screens. The pricing is provided below:

URINE DIP TEST PRICING:

11 Panel on-site dip test: $3.25/device, minimum order 25 tests

6 panel on-site dip test: $1.75/device, minimum order 25 tests

4 panel on-site dip test: $1.20/device, minimum order 25 tests

K2/Spice single dip test, may be purchased separately for $4.00/device, minimum order is 25 tests

ALL INCLUSIVE URINE CUP PRICING:

11 Panel cup: $3.81/cup, minimum order 25 tests*

11 Panel cup to include K2: $7.75/cup, minimum order 25 tests

6 panel cup: $2.65/cup, minimum order 25 tests*

6 Panel cup to include K2: $6.45/cup, minimum order 25 tests

4 Panel cup: $2.30/cup, minimum order 25 tests

4 panel cup to include K2: $5.65/cup, minimum order 25 tests

NOTE: Sample Validity Test for Creatinine, Specific Gravity and pH can be added to any cup for an additional: $.45/device

*As quoted on price guide included in RFP

ORAL FLUID ON-SITE DEVICES:

10 Panel devices: $9.95/tests, minimum order 25 tests

6 Panel devices: $6.50/test, minimum order 25 tests

**K2/Spice single urine dip test may be purchased separately for $4.00/device

**At this time there are no on-site oral fluid devices available with K2/Spice or any other synthetic drug. We are currently working on developing such a device.

Premier Biotech, Inc Bid Response
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Company Information:

Premier Biotech, Inc is a small, independent, woman owned business whose main offices are based in Minnesota. We have been in business since 2009. Premier Biotech, Inc. is a provider of quality, innovative drugs of abuse and alcohol screening devices. We offer an extensive and flexible range of products from a single dip tests for 16 individual drugs to multi panel cards and multi panel cups that test for a vast range of drugs simultaneously. With the wide range of the products we offer and the extensive knowledge of our staff in the drug of abuse screening industry, we have successfully developed programs with many state and local government agencies.

Premier Biotech is focused on delivering cutting edge technology in drugs of abuse testing. We are one of the first in the market to offer an onsite single screen for K2/Spice in urine. We offer this in a single format as well as in several multi panel cups and dip tests. It is not yet available in saliva, but the research is being conducted.

In addition to offering a top quality, innovative, customizable product line, Premier Biotech is committed to delivering exceptional customer experience. At the request of the State, Premier Biotech will set up a custom web based ordering portal designated solely for DJS orders, with links to all training and product information being offered.

Product Specifications:

Levels of Detection for Premier Biotech on-site urine screens cup with K2:

Test	Calibrator	Cut-off (ng/ml)
AMP	d-Amphetamine	1000
BAR	Secobarbital	300
BUP	Buprenorphine	10
BZO	Oxazepam	300
COC	Benzoylecgonine	300
K2/Spice	JWH-018/JWH-073	50
MDMA	3,4-methylenedioxymethamphetamine	500
MET	d-Methamphetamine	1000
MTD	dl-Methadone	300
OPI300	Morphine	300
OPI	Morphine	2000
OXY	Oxycodone	100
PCP	Phencyclidine	25
PPX	Propoxyphene	300
TCA	Nortriptyline	1000
THC	11-nor-9-THC-9-COOH	50

Premier Biotech's cup with K2 is an all inclusive device with all drugs clearly marked and housed in individual channels. They are an immunoassay based screen for drugs of abuse that meet SAMHSA cut off levels. All strips have a built in control to help ensure device is functioning properly. A temperature strip is included on all cups. We have the ability to modify to the screens to DJS's needs. Alcohol can be added to any device for an additional charge.

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Levels of Detection for Premier Biotech on-site urine screens dip tests (K2 not included):

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

Premier Biotech's dip test is card like device with all drugs clearly marked and housed in individual chambers. They are an immunoassay based screen for drugs of abuse that meets the SAMHSA cut-off levels for all drugs. All strips have a built in control to help ensure device is functioning properly.

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Levels of Detection for Premier Biotech on-site oral fluid screens*:

Test	Calibrator	Cut-off (ng/mL)
Amphetamine (AMP)	D-Amphetamine	50
Benzodiazepine (BZO)	Oxazepam	10
Buprenorphine (BUP)	Buprenorphine	5
Cocaine (COC)	Benzoylecgonine	20
Cotinine (COT)	Cotinine	50
EDDP (EDDP)	2-Ethyliden-1,5-Dimethyl-3,3-Diphenylpyrrolidine	20
Ketamine (KET)	Ketamine	50
Marijuana (THC)	11-nor-Δ9-THC-9 COOH	12
Marijuana (THC)	Δ9-THC	50
Methadone (MTD)	Methadone	30
Methamphetamine (MET)	D-Methamphetamine	50
Opiates (OPI)	Opiates	40
Oxycodone (OXY)	Oxycodone	40
Phencyclidine (PCP)	Phencyclidine	10
Propoxyphene (PPX)	Propoxyphene	50
Barbiturate (BAR)	Barbiturate	50

Premier Biotech's Oral Detect product is an innovative one step saliva drug screen that has the ability to test up to 10 drugs simultaneously, with all drugs clearly marked and housed in individual channels. Each strip has a built in control to ensure the test is functioning properly. There is no need for additives or buffer solution. The Oral Detect can be modified to meet DJS's needs.

***Please note that at this time K2 is not available in on-site saliva testing. We are still in the development stages.**

Qualifications of Offeror:

Premier Biotech, Inc has been working successfully with several Nationwide Accounts, several well known staffing agencies, as well as many individual federal, state and local government agencies. Premier Biotech is in process of applying for a GSA contract which in turn will enable us to work with MMCAP facilities as well.

Premier Biotech takes the needs of its customers very seriously and works diligently to meet and exceed their customer needs. References will be supplied upon request of the State.

Premier Biotech, Inc Bid Response
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General Terms and Conditions:

1. Contractual Agreement: Premier Biotech agrees that any Purchase Orders issued and signed by the Purchasing Division Director or his designee, and approved as to form by the Attorney General's Office is acceptance of this Contract, and that Premier Biotech's signature on this bid signifies that we accept the terms and conditions of this Contract.

2. Definitions: Premier Biotech understands all definitions given

3. Contract Term; Renewal; Extension: Premier Biotech understands this is Contract is a one year contract, and is limited to two successive one year extensions. And that with the sole discretion of the Purchasing Division Director, the contract may be extended for a reasonable time after initial contract term as may necessary to obtain a new contract or vendor

4. Quantities: Premier Biotech understands that the quantities listed in this Solicitation are only approximations and the Contract shall cover the quantities actually ordered and delivered to the agencies.

5. Pricing: Premier Biotech agrees that the pricing set forth in this Contract is firm for the life of the Contract, unless specified elsewhere in the Solicitation/Contract. It is also understood that any inclusion of price adjustment provisions may result in disqualification.

6. Emergency Purchases: Premier Biotech understands and agrees.

7. Required Documents: Premier Biotech will supply all documents at the time the State requests

8. Litigation Bond: Premier Biotech understands and agrees

9. Alternates: Premier Biotech understands and agrees that all products bid within this solicitation will be provided as specified and if at any time a substitution would be required prior authorization will be obtained from the State.

10. Exceptions and Clarifications: Premier Biotech understands and agrees

11. Liquidated Damages: Premier Biotech understands and agrees

12. Acceptance/Rejection: Premier Biotech agrees that the State has the right to accept or reject any bid and that the signature on this bid is acceptance of the terms and conditions within this Solicitation and is bound by the terms of the contract as reflected in the Purchase Order, upon receipt.

13. Registration: Premier Biotech is registered and has paid the applicable fees.

14. Communication Limitations: Premier Biotech agrees and understands there has been no communications with any State employees regarding this Solicitation other then except through the Purchasing Division.

15. Funding: Premier Biotech understands and agrees

16. Payment: Premier Biotech understands and agrees that payment may only be received after product has been shipped and invoice has been sent to appropriate facility.

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17. Unit Price: Premier Biotech agrees that the unit price in this Solicitation will prevail in all matters
18. Delivery: Premier Biotech agrees all quoted prices include UPS Ground shipping charges. Any express shipping requested by the State will incur additional shipping fees.
19. Interest: Premier Biotech understands that the State will not pay interest fees.
20. Preference: Premier Biotech understands and agrees. No preferences are being requested
21. Small, Woman-Owned, or Minority-Owned Business: Premier Biotech is a Woman-Owned business, but has not at this point, received certification as such from any government agency.
22. Taxes: Premier Biotech understands that all taxes are the responsibility of the Vendor
23. Cancellation: Premier Biotech understands and agrees.
24. Waiver of Minor Irregularities: Premier Biotech understands and agrees.
25. Time: Premier Biotech agrees
26. Applicable Law: Premier Biotech understand and agrees
27. Compliance: Premier Biotech acknowledges that by signing this bid it understands and will comply with all applicable, federal, state and local laws
28. Prevailing Wage: Not applicable, Premier Biotech does not have any subcontractors.
29. Arbitration: Premier Biotech understands and agrees.
30. Modifications: Premier Biotech understands that this writing is the final expression of intent and that no modifications may be made without the written approval from the Purchasing Division and the Attorney General's office. The Vendor will not implement any changes until such written approval has been obtained
31. Waiver: Premier Biotech understands that any waiver of the provisions in this Contract must be submitted in writing and be signed by the waiving party
32. Subsequent Forms: Premier Biotech understands and agrees that only the terms and conditions contained in this Contract are binding above all other terms and conditions that may appear on any Purchasing forms received from the state.
33. Assignment: Premier Biotech agrees and understands
34. Warranty: Premier Biotech warrants that a.) The drug screens it provides DJS will conform to specifications within this solicitation; b.) Will be fit for the purpose intended; c.) all goods will be free from defect in material and workmanship
35. State Employees: Premier Biotech understands this contract is not to be used for personal matters by any state employee

Premier Biotech, Inc Bid Response
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36. Bankruptcy: Premier Biotech understands and agrees

37. HIPPA Business Associate Addendum: Premier Biotech has read addendum and understands, although it does not apply to Premier Biotech as we offering onsite devices

38. Confidentiality: Premier Biotech agrees and understands

39. Disclosure: Premier Biotech understands that any information submitted with this solicitation will be made public. If any information is confidential it will be marked as such.

40. Licensing: Premier Biotech understands and agrees.

41. Antitrust: Premier Biotech understands and agrees.

42. Vendor Certifications: Premier Biotech agrees that by signing this bid and entering into this Contract, 1.) the bid was made with no prior understanding, agreement or connection with any other agency, company etc submitting a bid for the same supplies. 2.) Premier's bid is fair and without collusion or fraud. 3) This Contract is entered into without prior understanding or connection to any other agency that may be considered violation of law. 4) Premier has reviewed the RFQ, understands the requirements, terms and conditions and other information contained herein. Also that the signature on this bid affirms that no one associated with Premier Biotech has any interest nor shall acquire interest which would compromise the performance of its products.

43. Purchase Card Acceptance: Premier Biotech has the ability to accept any major credit (purchase) cards and understands that it must accept the West Virginia Purchasing Card for all orders.

44. Vendor Relationship: Premier Biotech understands and agrees that it is to be considered an independent contractor by the State and that all employees no employed or to be employed to work with the State are the sole responsibility of Premier Biotech. None of it's' employees will now or in the future be considered employees of the State.

45. Indemnification: Premier Biotech agrees to indemnify, defend and hold harmless the State, Agency, their officers, and employees from and against: 1) claims or losses for services rendered by any of its employees. 2) Claims or losses resulting to any persons associated with the State, by its employees for any publication, translation, reproduction, delivery, performance, use or disposition of data used under the contract in any manner not authorized in the Contract or by Federal or State regulations. 3) Any failure of the Vendor or any of its employees to observe State and Federal laws to include, labor and wage and hour laws.

46. Purchasing Affidavit: Premier Biotech has signed and returned the required Purchasing Affidavit

47. Additional Agency and Local Government Use: Premier Biotech understands that this Contract will extend to other agencies other the DJS and is happy to extend the pricing, terms and conditions to those other agencies.

48. Conflict of Interest: Premier Biotech agrees. There are no conflicts of interest and if any shall arise the State will be notified immediately.

Premier Biotech, Inc Bid Response
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49. Background Check: Premier Biotech understands and agrees. It will have no reason to be on the State grounds or to have access to any sensitive information. This response is solely for onsite drug screen devices to be performed on premise by DJS.

THC			
11-nor-D9-THC-9-COOH	50	D9-tetrahydrocannabinol	5,000
11-hydroxy-D9-THC	1,000	Cannabinol	10,000
D8-tetrahydrocannabinol	5,000	Cannabidiol	>100,000
Tricyclic Antidepressant			
Nortriptyline	1,000	Promazine	1,500
Nordoxepin	2,000	Desipramine	400
Trimipramine	2,000	Doxepin	3,000
Amitriptyline	1,500	Maprotiline	2,000

d.Interference

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

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

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

e.Effect of Specimen pH

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

f.Effect of Specimen Specific Gravity

Drug sample solutions with 50% below and 50% above cutoff concentrations were adjusted to specific gravity 1.003-1.04 and tested using Premier Cup.

An unaltered sample was used as a control. The results demonstrate that varying ranges of specimen specific gravity do not interfere with the performance of the test.

ADULTERATION TESTS

Specimen validity/adulteration tests are not in vitro diagnostic assays. Therefore, information regarding these tests is not subject to FDA review.

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

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

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

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

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

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

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

GL: Glutaraldehyde is not a normal component of human urine and it should not be present in normal urine. The presence of glutaraldehyde in the urine sample indicates the possibility of adulteration. However, false positives may result when ketone bodies are present in the urine. Ketone bodies may appear in urine when a person is in ketoacidosis due to starvation or other metabolic abnormalities.

ASSAY PROCEDURE FOR ADULTERATION TEST

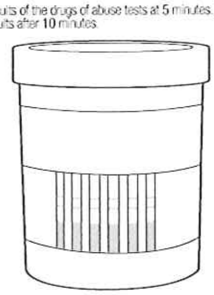
Preparation

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

Testing (Please refer to the color chart)

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

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



Premier Cup

BIBLIOGRAPHY OF SUGGESTED READING

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

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

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

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

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

Manufactured for:

Premier Biotech
6630 Lakeway Drive
Chanhassen MN 55217

PB112E-FUO February 2012

Premier BIOTECH

Premier Cup

FORENSIC USE ONLY

INTENDED USE

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

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

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

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

SUMMARY AND EXPLANATION

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

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

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

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

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

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

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

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

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

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

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

Tetrahydrocannabinol (THC) is generally accepted to be the principle active component in marijuana. When ingested or smoked, it produces euphoric effects. Abusers exhibit central nervous system effects, altered mood and sensory perceptions, loss of coordination, impaired short term memory, anxiety, paranoia, depression, confusion, hallucinations and increased heart rate. When marijuana is ingested, the drug is extensively metabolized by the liver, the primary metabolite of marijuana excreted in the urine is 11-nor-D-9-tetrahydrocannabinol-9-carboxylic acid. The elimination of THC and metabolites in urine is highly dependent on frequency of drug use and the physiology of the user.

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

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

TEST PRINCIPLE

The Premier Cup is based on the principle of competitive immunochemical reaction between a chemically labeled drug (drug-protein conjugate) and the drug or drug metabolites which may be present in the urine sample for the limited antibody binding sites. The test contains a nitrocellulose membrane strip pre-coated with drug-protein conjugate in the test region and a pad containing colored antibody-colloidal gold conjugate. During the test, the urine sample is allowed to migrate upward and rehydrate the antibody-colloidal

gold conjugate. The mixture then migrates along the membrane chromatographically by the capillary action to the immobilized drug-protein band on the test region. When drug is absent in the urine, the colored antibody-colloidal gold conjugate and immobilized drug-protein bind specifically to form a visible line in the test region as the antibody complexes with the drug-protein.

When drug is present in the urine, it will compete with drug-protein for the limited antibody sites. The line on the test region will become less intense with increasing drug concentration. When a sufficient concentration of drug is present in the urine, it will fill the limited antibody binding sites. This will prevent attachment of the colored antibody-colloidal gold conjugate to the drug-protein on the test region. Therefore, the presence of the line on the test region indicates a negative result for the drug and the absence of the test line on the test region indicates a positive result for the drug.

A visible line generated by a different antigen/antibody reaction is also present at the control region of the test strip. This line should always appear, regardless of the presence of drugs or metabolites in the urine sample. This means that a negative urine sample will produce both 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 devices. Each device consists of different test strips in a plastic test strip holder. The test strip contains a colloidal gold pad coated with antibody and rabbit antibody. It also contains a membrane coated with drug- protein conjugate in the test band and goat anti-rabbit antibody in the control band. For the device with adulteration test, an adulteration test strip is also included in each device.
- One instruction sheet
- Security seals (if applicable)
- Adulteration Color Chart (when applicable)

MATERIAL REQUIRED BUT NOT PROVIDED

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

WARNINGS AND PRECAUTIONS

- For forensic use only.
- Urine specimens may be potentially infectious. Proper handling and disposal methods should be established.
- Avoid cross-contamination of urine samples by using a new specimen collection container for each urine sample.
- Test device should remain sealed until ready for use.
- Do not use the test kit after the expiration date.
- A positive test result does not always mean an individual has taken the drug illegally as the drug can be administered legally.
- Do not store and or expose reagent kits at temperature greater than 30°C. Do not freeze.

STORAGE

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

SPECIMEN COLLECTION AND HANDLING

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

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

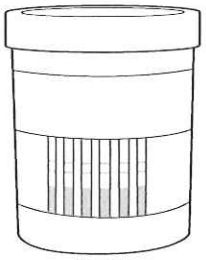
ASSAY PROCEDURE FOR DRUG TEST

Preparation

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

Testing

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



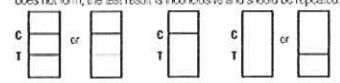
Premier Cup

INTERPRETATION OF RESULTS

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

Positive (+): A colored line appears at the control region 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 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 device. A line must form in the Control band region regardless of the presence or absence of drugs or metabolites. The presence of the line in the Control region indicates that sufficient sample volume has been used and that the reagents are migrating properly. If the line in the Control region does not form, the test is considered invalid and must be repeated.

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

LIMITATIONS OF PROCEDURE

- The assay is designed for use with human urine only.
- A positive result with any of the tests indicates only the presence of a drug/metabolite and does not indicate or measure intoxication.
- There is a possibility that 'technical' or procedural error as well other substances as factors not listed may interfere with the test and cause false results. See SPECIFICITY 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 new sample.

PERFORMANCE CHARACTERISTICS

A. Accuracy

The accuracy of the Premier Cup was evaluated in comparison to commercially available drug screen tests and GC/MS. Sixty (60) negative urine samples collected from presumed non-user volunteers were tested by both Premier Cup and commercially available drug screen tests.

Of these negative urine samples tested, all were correctly identified as negative by both methods. In a separate study, positive urine samples, obtained from clinical laboratories where the drug concentrations were determined by GC/MS (HPLC for TCA), were tested by Premier Cup and commercial drug screen tests. The results of accuracy study are presented below:

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

B. Precision

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

B. Specificity

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

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

Compound	Conc. (ng/ml)	Compound	Conc. (ng/ml)
Amphetamine			
d-Amphetamine	1,000	d-Methamphetamine	50,000
dl-Amphetamine	2,500	(+/-)3,4-MDMA	50,000
(+/-)3,4 MDA	1,250		
Barbiturates			
Secobarbital	300	Butabarbital	400
Allobarbital	600	Butalbital	300
Mephenal	200	Butethal	450
Amobarbital	1500	Pentobarbital	400
Aprobarbital	300	Phenobarbital	450
Barbital	1500		
Benzodiazepines			
Oxazepam	300	Flunitrazepam	300
Mirazaklam	400	Flurazepam	300
Bromazepam	250	Lorazepam	500
Chlordiazepoxide	300	Medazepam	300
Diclazam	1000	Nitrazepam	250
Clonazepam	500	Nordiazepam	150
Clorazepate	150	Prazepam	500
Desalkylflurazepam	200	Temazepam	200
Diazepam	450	Triazolam	450
Estazolam	300		
Buprenorphine			
Buprenorphine	10	Buprenorphine-3-beta D-glucuronide	7.5
Norbuprenorphine	2500	Norbuprenorphine-3-beta D-glucuronide	150
Codeine	>100,000		
Morphine	>100,000		
Naloxphine	10,000		
Cocaine Metabolite(150)			
Benzoylecgonine	150	Cocaethylene	>100,000
Cocaine	5,000	Ecgonine methyl esters	>100,000
Ecgonine	>100,000		
Cocaine Metabolite (300)			
Benzoylecgonine	300	Cocaine	300
Methamphet-amine (500)			
d-Methamphetamine	500	(+/-)3,4 MDMA	2,000
d-Amphetamine	50,000	l-Methamphetamine	10,000
l-Amphetamine	>100,000	Ephedrine	50,000
(+/-)3,4 MDEA	50,000	Mephentermine	50,000
(+/-)3,4 MDA	100,000		
Methamphet-amine (1000)			
d-Methamphetamine	1000	(+/-)3,4 MDMA	3,000
d-Amphetamine	50,000	l-Methamphetamine	10,000
l-Amphetamine	>100,000	Ephedrine	>100,000
(+/-)3,4 MDEA	50,000	Mephentermine	75,000
(+/-)3,4 MDA	100,000		
MDMA			
(+/-)3,4 MDMA	500	(+/-)3,4 MDA	4,000
(+/-)3,4 MDEA	450		
Methadone			
(+/-) Methadone	300	Methadol	1,500
Oplates (300)			
Morphine	300	Hydrocodone	500
Codeine	250	Hydromorphone	500
Ethylmorphine	300	Morphine-3-glucuronide	300
Heroin	750	Naloxphine	5,000
Oplates (2000)			
Morphine	2,000	Hydrocodone	4,000
Codeine	2,000	Hydromorphone	5,000
Ethylmorphine	1,000	Morphine-3-glucuronide	2,500
Heroin (diacetylmorphine)	5,000	Naloxphine	5,000
Oxycodone			
Oxycodone	100	Morphine	>100,000
Hydrocodone	5000	Codeine	50,000
Hydromorphone	50,000	Naloxphine	5,000
PCP			
Phencyclidine	25	Tenocyclidine	2,000
PPX			
d-Propoxyphine	300	d-Norpropoxyphene	300

One Step Drug of Abuse Test

(Strip, dipcard, cassette, cup)

Package Insert for Multi Drug Screen Test

This Instruction Sheet is for testing of any combination of the following drugs:
AMP/BAR/BZO/COC/THC/MTD/mAMP/MDMA/MOR/OPI/OXY/PCP/TCA
Including Adulterant Tests (Specimen Validity Tests) for :
Oxidants (OX), Specific Gravity (S.G.) , pH, Creatinine (CRE), Nitrite (NIT) and Glutaraldehyde (GLU)

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

For Professional and *In Vitro* Diagnostic Use Only.

INTENDED USE

The One Step Drug of Abuse Test 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)	D-Amphetamine	1,000 ng/mL
Barbiturates (BAR)	Secobarbital	300 ng/mL
Benzodiazepines (BZO)	Oxazepam	300 ng/mL
Cocaine (COC)	Benzoylecgonine	300 ng/mL
Marijuana (THC)	11-nor-Δ⁹-THC-9 COOH	50 ng/mL
Methadone (MTD)	Methadone	300 ng/mL
Methamphetamine (mAMP)	D-Methamphetamine	1,000 ng/mL
Methylenedioxymethamphetamine (MDMA)	D,L-Methylenedioxymethamphetamine	500 ng/mL
Opiate 300 (OPI 300 MOP MOR)	Morphine	300 ng/mL
Opiate 2000 (OPI 2000)	Morphine	2,000 ng/mL
Oxycodone (OXY)	Oxycodone	100 ng/mL
Phencyclidine (PCP)	Phencyclidine	25 ng/mL
Tricyclic Antidepressants (TCA)	Nortriptyline	1,000 ng/mL

This assay provides only a preliminary qualitative test result. Use a more specific alternate quantitative analytical method to obtain a confirmed analytical result. Gas chromatography/mass spectrometry (GC/MS) is the preferred confirmatory method. Apply clinical and professional judgment to any drug of abuse test result, particularly when preliminary positive results are obtained.

SUMMARY AND EXPLANATION OF THE TEST

The One Step Drug of Abuse Test is a competitive immunoassay utilizing highly specific reactions between antibodies and antigens for the detection of multiple drugs and drug metabolites in human urine.

The One Step Drug of Abuse Test is a rapid urine screening test that utilizes monoclonal antibodies to selectively detect elevated levels of specific drugs in urine without the use of an instrument.

AMPHETAMINE (AMP)
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 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 Drug of Abuse Test yields a positive result when Amphetamines in urine exceed 1,000 ng/mL. This is the suggested screening cut-off for positive specimens set by the Substance Abuse and Mental Health Services Administration (SAMHSA, USA).

BARBITURATES (BAR)
Barbiturates are central nervous system depressants. They are used therapeutically as sedatives, hypnotics, and anticonvulsants. Barbiturates are almost always taken orally as capsules or tablets. The effects resemble those of intoxication with alcohol. Chronic use of barbiturates leads to tolerance and physical dependence. Short acting Barbiturates taken at 400 mg/day for 2-3 months 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
The One Step Drug of Abuse Test yields a positive result when the Barbiturates in urine exceed 300 ng/mL.

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 the Benzodiazepines in the urine is 3-7 days.
The One Step Drug of Abuse Test yields a positive result when the Benzodiazepines in urine exceed 300 ng/mL.

COCAINE (COC)
Cocaine is a potent central nervous system (CNS) 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. 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.
The One Step Drug of Abuse Test yields a positive result when the cocaine metabolite in urine exceeds 300 ng/mL. This is the suggested screening cut-off for positive specimens set by the Substance Abuse and Mental Health Services Administration (SAMHSA, USA).

MARIJUANA (THC)
THC (Δ⁹-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-Δ⁹-tetrahydrocannabinol-9-carboxylic acid (Δ⁹-THC-COOH).
The One Step Drug of Abuse Test 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).

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.
The One Step Drug of Abuse Test yields a positive result when the Methadone in urine exceeds 300 ng/mL.

METHAMPHETAMINE (mAMP)
Methamphetamine is an addictive stimulant drug that strongly activates certain systems in the brain. Methamphetamine is closely related chemically to amphetamine, but the central nervous system 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 central nervous system 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 delaminated 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 Drug of Abuse Test yields a positive result when the Methamphetamine in urine exceeds 1,000 ng/mL.

METHYLENEDIOXYMETHAMPHETAMINE (MDMA)
Methylenedioxymethamphetamine (ecstasy) is a designer drug first synthesized in 1914 by a German drug company for the treatment of obesity. 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 Drug of Abuse Test yields a positive result when the Methylenedioxymethamphetamine in urine exceeds 500 ng/mL.

OPIATE (OPI 300,MOP,MOR)
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 central nervous system. 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.
The One Step Drug of Abuse Test yields a positive result when the concentration of opiate exceeds the 300 ng/mL cut-off level.

OPIATE (OPI 2000)
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 central nervous system. 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.
The One Step Drug of Abuse Test yields a positive result when the 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)

OXYCODONE (OXY)

Oxycodone, [4,5-epoxy-14-hydroxy-3-methoxy-17-methyl-morphinan-6-one, dihydrohydroxycodeinone] is a semi-synthetic opioid agonist derived from thebaine, a constituent of opium. Oxycodone is a Schedule II narcotic analgesic and is widely used in clinical medicine. The pharmacology of oxycodone is similar to that of morphine, in all respects, including its abuse and dependence liabilities. Pharmacological effects include analgesia, euphoria, feelings of relaxation, respiratory depression, constipation, pupillary constriction, and cough suppression. Oxycodone is prescribed for the relief of moderate to high pain under pharmaceutical trade names as OxyContin® (controlled release), OxyIR®, OxyFast®(immediate release formulations), or Percodan® (aspirin) and Percocet® (acetaminophen) that are in combination with other nonnarcotic analgesics. Oxycodone's behavioral effects can last up to 5 hours. The controlled-release product, OxyContin®, has a longer duration of action (8-12 hours).

The One Step Drug of Abuse Test yields a positive result when the Oxycodone in urine exceeds 100 ng/mL.

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.

Phencyclidine is used in powder, capsule, and tablet form. The powder is either snorted or smoked after mixing it with marijuana or vegetable matter. Phencyclidine 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 Phencyclidine.

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.[1] Phencyclidine is excreted in the urine as an unchanged drug (4% to 19%) and conjugated metabolites (25% to 30%).[1]

The One Step Drug of Abuse Test yields a positive result when the phencyclidine level 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).

TRICYCLIC ANTIDEPRESSANTS (TCA)

TCA (Tricyclic Antidepressants) are commonly used for the treatment of depressive disorders. TCA overdoses can result in profound central nervous system 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 Drug of Abuse Test yields a positive result when the concentration of Tricyclic Antidepressants in urine exceeds 1,000 ng/mL.

ADULTERANT TESTS (SPECIMEN VALIDITY TESTS) SUMMARY

The Adulterant Test Strip contains chemically treated reagent pads. Observation of the color change on the strip compared to the color chart provides a semi-quantitative screen for oxidants, specific gravity, pH, creatinine, nitrite and glutaraldehyde in human urine which can help to assess the integrity of the urine specimen.

ADULTERATION

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

- Oxidants (OX): Tests for the presence of oxidizing agents such as bleach and peroxide in the urine.
- Specific Gravity (S.G.): Tests for sample dilution. Normal levels for specific gravity will range from 1.003 to 1.030. Specific gravity levels of less than 1.003 or higher than 1.030 may be an indication of adulteration or specimen dilution.
- 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 below pH 4.0 or above pH 9.0 may indicate the sample has been altered.
- Nitrite (NIT): Tests for commercial adulterants such as Klear and Whizzies. Normal urine specimens should contain no trace of nitrite. Positive results for nitrite usually indicate the presence of an adulterant.
- Glutaraldehyde (GLU): Tests for the presence of an aldehyde. Glutaraldehyde is not normally found in a urine specimen. Detection of glutaraldehyde in a specimen is generally an indicator of adulteration.
- Creatinine (CRE): Creatinine is one way to check for dilution and flushing, which are the most common mechanisms used in an attempt to circumvent drug testing. Low creatinine may indicate dilute urine.

PRINCIPLE

The One Step Drug of Abuse Test 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 line 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 line region.

A drug-positive urine specimen will not generate a colored line in the specific test line region of the strip because of drug competition, while a drug-negative urine 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 a membrane strip 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, Cocaine, Methamphetamine, Methylenedioxymethamphetamine, Morphine, THC, Phencyclidine, Benzodiazepines, Methadone, Barbiturates, Tricyclic Antidepressants, Opiate or Oxycodone.

ADULTERANT TESTS (SPECIMEN VALIDITY TESTS) REAGENTS

Adulteration Pad	Reactive Indicator	Buffers and Non-reactive Ingredients
Oxidants (OX)	0.36%	99.64%
Specific Gravity (S.G.)	0.25%	99.75%
pH	0.06%	99.94%
Nitrite (NIT)	0.07%	99.93%
Glutaraldehyde (GLU)	0.02%	99.98%
Creatinine (CRE)	0.04%	99.96%

PRECAUTIONS

- For Professional Use Only.
- For In Vitro Diagnostic Use Only.
- Do not use after the expiration date.
- The test panel should remain in the sealed pouch until use.
- The test is for single use.
- While urine is not classified by OSHA or the CDC as a biological hazard unless visibly contaminated with blood [1], the use of gloves is recommended to avoid unnecessary contact with the specimen.
- The used test device and urine specimen 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 device must remain in the sealed pouch until use. DO NOT FREEZE. Do not use beyond the expiration date.

SPECIMEN COLLECTION AND PREPARATION

Urine Assay

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

SPECIMEN STORAGE

Urine specimens may be stored at 2-8°C (36-46°F) 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 device • Desiccants • Package insert • Procedure card (for cup use only) • Color chart card for adulterant interpretation (when applicable) • Dropper (for cassette)

Materials Required but Not Provided

• Specimen collection container (for strip, cassette, dipcard) • Disposable gloves • 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.

[For Strip]

1) Remove the strip from the foil wrapper or the desiccated container (bring the container to the room temperature before opening to avoid condensation of moisture in container). Label the strip with patient or control identifications.
2) Immerse the strip into the urine with the arrow end pointing toward the urine. Do not cover the urine over the MAX (maximum) line. You may leave the strip in the urine or you may take the strip out after a minimum of 15 seconds in the urine and lay the strip flatly on a non absorptive clean surface.
3) Read results at 5 minutes.

DO NOT INTERPRET RESULT AFTER 10 MINUTES.

[For Cassette]

1) Remove the test device from its foil wrapper by tearing along the slice (bring the container to the room temperature before opening to avoid condensation of moisture in container). Label the device with patient or control identifications.
2) Using the specimen dropper, withdraw the urine sample from the specimen cup and slowly dispense 3 drops (approximately 120uL) into the circular sample well, being careful not to overfill the absorbent pad.
3) Read results at 5 minutes. DO NOT INTERPRET RESULT AFTER 10 MINUTES.

[For Dipcard]

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 5 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 10 MINUTES.

[For Multi-Drug Screen Test Cup]

Please follow the instructions on the Procedure Card.

This illustration shows a multi-drug screen test cup with a built-in test dipcard.

INTERPRETATION OF RESULTS

(Please refer to the previous illustration)

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

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

POSITIVE: One color line appears in the control region (C). No line appears in the test region (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 device. If the problem persists, discontinue using the lot immediately and contact your supplier.

ADULTERANT TESTS (SPECIMEN VALIDITY TESTS) INTERPRETATION

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

ADULTERANT TESTS (SPECIMEN VALIDITY TESTS) LIMITATIONS

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

QUALITY CONTROL

A procedural control is included in the test. A color 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 One Step Drug of Abuse Test 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.[1,1]
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 and a new test device.
4. A Positive result does not indicate intoxication of the donor, the concentration of drug in the urine, or the route of drug administration.
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. 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.

PERFORMANCE CHARACTERISTICS

Accuracy

A side-by-side comparison study was conducted using One Step Drug of Abuse Test and other commercially available rapid drug test. Testing was performed on clinical urine samples quantified by GC/MS method for each of the following drug. Results are summarized below.

Test	Compounds Contributed to the Totals of GC/MS
AMP	Amphetamine
BAR	Secobarbital
BZO	Oxazepam
COC	Benzoylecgonine
THC	11-nor-Δ9-tetrahydrocannabinol-9-carboxylic acid
MTD	Methadone
mAMP	Methamphetamine
MDMA	D,L-Methylenedioxymethamphetamine, Methylenedioxymethamphetamine
OPI, MOP	Morphine, Codeine
OXY	Oxycodone
PCP	Phencyclidine
TCA	Nortriptyline

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% Agreement with GC/MS (HPLC for TCA)

	AMP	mAMP	OPI 2000	OPI 300	COC	PCP	THC
Positive Agreement	95%	96%	>99%	96%	96%	95%	96%
Negative Agreement	>99%	>99%	97%	>99%	>99%	>99%	>99%
Overall Agreement	98%	98%	98%	98%	98%	95%	98%

	BAR	TCA	MDMA	BZO	MTD	OXY
Positive Agreement	97%	98%	93%	96%	94%	95%
Negative Agreement	98%	>99%	>99%	>99%	98%	>99%
Overall Agreement	98%	99%	96%	98%	96%	98%

Analyte	BAR		MDMA		BZO		MTD		OXY		TCA		THC	
	Pos	Neg	Pos	Neg	Pos	Neg	Pos	Neg	Pos	Neg	Pos	Neg	Pos	Neg
Negative Samples	0	4	0	4	0	5	0	3	0	4	0	4	0	0
Near Cut-off Negative Samples (between 50% of cut-off and cut off)	1	37	0	36	0	28	1	44	0	36	0	38	0	15
Near Cut-off Positive Samples (between cut-off and 150% of cut-off)	34	1	33	3	27	2	27	2	34	2	35	1	23	1
Positive Samples (>150% of cut-off)	3	0	4	0	18	0	3	0	4	0	4	0	1	0
Agreement with GC/MS	97%	98%	93%	>99%	96%	>99%	94%	98%	95%	>99%	98%	>99%	96%	>99%

Analyte	PCP		mAMP		OPI 300		OPI 2000		COC		AMP	
	Pos	Neg	Pos	Neg	Pos	Neg	Pos	Neg	Pos	Neg	Pos	Neg
Negative Samples	0	1	0	4	0	3	0	17	0	0	0	0
Near Cut-off Negative Samples (between 50% of cut-off and cut-off)	0	0	0	10	0	11	1	13	0	13	0	19
Near Cut-off Positive Samples (between cut-off and 150% of cut-off)	7	2	3	1	18	1	3	0	26	1	7	1
Positive Samples (>150% of cut-off)	28	0	22	0	7	0	6	0	0	0	13	0
Agreement with GC/MS	96%	>99%	96%	>99%	98%	>99%	>99%	97%	96%	>99%	95%	>99%

Reproducibility

Reproducibility studies were carried out using commercially available standards. Each standard was diluted in normal, drug-free urine to give the appropriate concentration. Each specimen, at each concentration of analyte, was tested four times daily, in duplicate, for five consecutive days. A total of 40 determinations were made at each concentration. The results are given below.

Amphetamine (AMP)

Amphetamine(AMP) conc (ng/mL)	Total number of Determinations	Result	Precision
No drug present	40	40 negative	>99%
500	40	40 negative	>99%
750	40	40 negative	>99%
1,000	40	40 positive	>99%
1,500	40	40 positive	>99%

Barbiturates (BAR)

Secobarbital conc (ng/mL)	Total number of Determinations	Result	Precision
No drug present	40	40 negative	>99%
150	40	40 negative	>99%
225	40	40 negative	>99%
300	40	40 positive	>99%
450	40	40 positive	>99%

Benzodiazepines (BZO)

Oxazepam conc (ng/mL)	Total number of Determinations	Result	Precision
No drug present	40	40 negative	>99%
150	40	40 negative	>99%
225	40	40 negative	>99%
300	40	40 positive	>99%
450	40	40 positive	>99%

Cocaine (COC)

Benzoylecgonine conc (ng/mL)	Total number of Determinations	Result	Precision
No drug present	40	40 negative	>99%
150	40	40 negative	>99%
225	40	40 negative	>99%
375	40	40 positive	>99%
450	40	40 positive	>99%

Marijuana (THC)

11-nor-Δ9-THC-9-COOH conc (ng/mL)	Total number of Determinations	Result	Precision
No drug present	40	40 negative	>99%
25	40	40 negative	>99%
37.5	40	40 negative	>99%
50	40	40 positive	>99%
75	40	40 positive	>99%

Methadone (MTD)

Methadone conc (ng/mL)	Total number of Determinations	Result	Precision
No drug present	40	40 negative	>99%
150	40	40 negative	>99%
225	40	40 negative	>99%
300	40	40 positive	>99%
450	40	40 positive	>99%

Methamphetamine (mAMP)

Methamphetamine conc (ng/mL)	Total number of Determinations	Result	Precision
No drug present	40	40 negative	>99%
500	40	40 negative	>99%
750	40	40 negative	>99%
1,000	40	40 positive	>99%
1,500	40	40 positive	>99%

Methylenedioxymethamphetamine (MDMA)

Methylenedioxymethamphetamine conc.(ng/mL)	Total number of Determinations	Result	Precision
No drug present	40	40 negative	>99%
250	40	40 negative	>99%
375	40	40 negative	>99%
500	40	40 positive	>99%
750	40	40 positive	>99%

Opiate 300 (OPI 300 MOP MOR)

Morphine conc.(ng/mL)	Total number of Determinations	Result	Precision
No drug present	40	40 negative	>99%
150	40	40 negative	>99%
225	40	40 negative	>99%
300	40	40 positive	>99%
375	40	40 positive	>99%

Opiate 2000 (OPI 2000)

Morphine conc.(ng/mL)	Total number of Determinations	Result	Precision
No drug present	40	40 negative	>99%
1,000	40	40 negative	>99%
1,500	40	40 negative	>99%
2,000	40	40 positive	>99%
3,000	40	40 positive	>99%

Oxycodone (OXY)

Oxycodone conc.(ng/mL)	Total number of Determinations	Result	Precision
No drug present	40	40 negative	>99%
50	40	40 negative	>99%
75	40	40 negative	>99%
100	40	40 positive	>99%
150	40	40 positive	>99%

Phencyclidine (PCP)

Phencyclidine conc.(ng/mL)	Total number of Determinations	Result	Precision
No drug present	40	40 negative	>99%
12.5	40	40 negative	>99%
19	40	40 negative	>99%
25	40	40 positive	>99%
37.5	40	40 positive	>99%

Tricyclic Antidepressants (TCA)

Nortriptyline conc.(ng/mL)	Total number of Determinations	Result	Precision
No drug present	40	40 negative	>99%
500	40	40 negative	>99%
750	40	40 negative	>99%
1,000	40	40 positive	>99%
1,500	40	40 positive	>99%

Analytical Sensitivity

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

Drug concentration Cut-off Range	n	AMP		BAR		BZO		COC		MOP	
		-	+	-	+	-	+	-	+	-	+
0% Cut-off	10	10	0	10	0	10	0	10	0	10	0
-50% Cut-off	10	10	0	10	0	10	0	10	0	10	0
-25% Cut-off	10	10	0	10	0	10	0	10	0	10	0
Cut-off	10	0	10	0	10	0	10	0	10	0	10
+50% Cut-off	10	0	10	0	10	0	10	0	10	0	10

Drug concentration Cut-off Range	n	THC		MTD		mAMP		MDMA	
		-	+	-	+	-	+	-	+
0% Cut-off	10	10	0	10	0	10	0	10	0
-50% Cut-off	10	10	0	10	0	10	0	10	0
-25% Cut-off	10	10	0	10	0	10	0	10	0
Cut-off	10	0	10	0	10	0	10	0	10
+50% Cut-off	10	0	10	0	10	0	10	0	10

Drug concentration Cut-off Range	n	OPI		OXY		PCP		TCA	
		-	+	-	+	-	+	-	+
0% Cut-off	10	10	0	10	0	10	0	10	0
-50% Cut-off	10	10	0	10	0	10	0	10	0
-25% Cut-off	10	10	0	10	0	10	0	10	0
Cut-off	10	0	10	0	10	0	10	0	10
+50% Cut-off	10	0	10	0	10	0	10	0	10

Analytical Specificity

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

Drug	Concentration(ng/ml)
AMPHETAMINE (AMP)	
d-amphetamine	1,000
DL-amphetamine	1,000
l-amphetamine	20,000
Phentermine	1,250
(+/-)- Methylenedioxyamphetamine (MDA)	1,500
BARBITURATES (BAR)	
Secobarbital	300
Amobarbital	300
Alphenal	150
Aprobarbital	200
Butabarbital	75
Butalbital	2,500
Butethal	100
Cyclopentobarbital	600
Pentobarbital	300
Phenobarbital	100
BENZODIAZEPINE (BZO)	
a-Hydroxyalprazolam	1,250
Alprazolam	200
Bromazepam	1,560
Chlordiazepoxide	1,565
Chlordiazepoxide HCl	780
Clobazam	100
Clonazepam	785
Clonazepate Dipotassium	195
Delorazepam	1,560
Desalkylflurazepam	390
Diazepam	195
Estazolam	2,500
Flunitrazepam	395
(±) Lorazepam	1,560
RS-Lorazepam glucuronide	160
Midazolam	12,500
Nitrazepam	95
Norchlordiazepoxide	200
Nordiazepam	390
Oxazepam	300
Temazepam	100
Triazolam	2,500
COCAINE (COC)	
Benzoylecgonine	300
Cocaethylene	300
Cocaine	300
Metoclopramide	60,000
Procaine	75,000
MARIJUANA (THC)	
11-Nor-a-Tetrahydrocannabinol	50
11-Hydroxy -a-Tetrahydrocannabinol	5,000
11-Nor-a-Tetrahydrocannabinol	50
11-Nor-a-Tetrahydrocannabinol-9 Carboxylic Glucuronide	2,500
a-Tetrahydrocannabinol	20,000
a-Tetrahydrocannabinol	20,000
METHADONE (MTD)	
Methadone	300
Doxylamine	50,000
METHAMPHETAMINE (mAMP)	
(+) 3,4-Methylenedioxy-n-ethylamphetamine(MDEA)	20,000
Procaine (Novocaine)	60,000
Trimethobenzamide	20,000
+l-methamphetamine	1,600
+methamphetamine	1000
Ranitidine (Zantac)	50,000
(+) 3,4 Methylenedioxymethamphetamine (MDMA)	2,500
METHYLENEDIOXYMETHAMPHETAMINE (MDMA)	
D,L-3,4 Methylenedioxymethamphetamine (MDMA)	500
3,4-Methylenedioxyamphetamine HCl (MDA)	3,000
3,4 Methylenedioxyethyl-amphetamine (MDEA)	300
OPIATES (OPI 300 MOP,MOR)	
6 acetylmorphine	500
Codeine	100
Eserine (Physostigmine)	15,000
Ethylmorphine	100
Heroin	500
Hydromorphone	2,000
Hydrocodone	1,250
Morphine	300
Morphine-3-glucuronide	75
Oxycodone	75,000
Thebaine	13,000

OPIATES (OPI 2000)	ng/mL
6-acetylmorphine	1,000
Codeine	800
Ethylmorphine	400
Heroin	10,000
Hydromorphone	2,000
Hydrocodone	5,000
Morphine	1,600
Morphine-3-glucuronide	1,000
Oxycodone	50,000
Thebaine	26,000
OXYCODONE (OXY)	
Oxycodone	100
Codeine	50,000
Dihydrocodeine	12,500
Ethylmorphine	25,000
Hydrocodone	1,580
Hydromorphone	12,500
Oxymorphone	1,580
Thebaine	50,000
PHENCYCLIDINE (PCP)	
Phencyclidine	25
4-Hydroxy PCP	90
PCP Morpholine	625
TRICYCLIC ANTIDEPRESSANTS (TCA)	
Notriptyline	1,000
Amitriptyline	1,500
Clomipramine	12,500
Desipramine	200
Doxepine	2,000
Imipramine	400
Maprotiline	2,000
Nordoxepine	1,000
Promazine	1,500
Promethazine	2,500
Trimipramine	3,000

EFFECT OF URINARY SPECIFIC GRAVITY

Fifteen (15) urine samples of normal, high, and low specific gravity ranges (1.005, 1.015, 1.03) were spiked with drugs at 50% below and 50% above cut-off levels respectively. The One Step Drug of Abuse Test 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 THE 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 Drug of Abuse Test. 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 Cocaine, Barbiturates, Benzodiazepines, Amphetamine, Morphine, Methamphetamine, Marijuana, Methadone, MDMA (Ecstasy), Opiates, Oxycodone, Phencyclidine or Tricyclic Antidepressants. The following compounds show no cross-reactivity when tested with the One Step Drug of Abuse Test at concentrations of 100 µg/mL.

NON CROSS-REACTING COMPOUNDS

Cocaine, Benzodiazepines, Amphetamine, Methamphetamine, Marijuana, Opiates, Morphine, Oxycodone, Phencyclidine, Barbiturates Non Cross-Reacting Compound
*Parent compound only

P00111111YDQX Rev

Acebutolol
Acetaldehyde
Acetaminophen
Acetamidophenol(N-Acetyl-p-aminophenol)
Acetazolamide
Acetone
Acetophenetidin
Acetopromazine
N-Acetyl-L-cysteine
N-Acetylprocainamide (Acedainide)
Acetylsalicylic Acid (Aspirin
Albumin, standard
Allobarbital (Diallylbarbituric Acid)
Allopurinol (4-Hydroxypyrazole(3,4- pyrimidine)
Alprenolol
Amantadine (Adamantan-1-amine)
Amcinonide
Amikacin
Amiloride
p-Aminobenzoic Acid
DL-Aminoglutethimide
Amiodarone
Amitryptyline
Ammonium Chloride
Amoxicillin
Amphotericin B
Ampicillin
Aniline
Antipyrine
Apomorphine
L-Ascorbic Acid
ASP-PHE-Methyl-Ester (Aspartame)
D-Aspartic Acid
DL-Aspartic Acid
L-Aspartic Acid
Baclofen
Barbituric Acid
Beclomethasone
Beclomethasone Dipropionate
Bendroflumethiazide
Benzidine
Benzilic Acid diethylaminoethyl ester
Benzocaine
Benzoic Acid
Benzphetamine
Benzthiazide
Benztropine
Benzyl alcohol
Benzylamine
Berberine
Betamethasone
Bilirubin
Brompheniramine
Bumetanide
Bupivacaine
Buprenorphine
Buspirone
Butacaine
Butyrophenone
Caffeine
Camphor
Canrenoic Acid
Captopril
Carbamazepine
Carbamyl-Carboplatin
Carisoprodol
Cefaclor
Cefadroxil
Cefotaxime
Cefoxitin
Ceftriaxone
Cefuroxime
Cephalexin
Cephaloridine
Cephradine
Chloramphenicol
Chlorcyclizine
Chloroquine
Chlorothiazide
Chlorotrianisene
Chlorpheniramine
Chlorpromazine
Chlorpropamide
Chlorprothixene
Chlorthalidone
Chlorzoxazone
Cholesterol
Cimetidine
Cinchonidine
Cinoxacin
Clemastine
Clenbuterol
Clindamycin
Clobetasone Butyrate
Clomipramine
Clonidine
Cloxacillin
Clozapine
Colchicine
Cortisone
Cortol
Creatinine
Cromolyn
Cyclobenzaprine
Cyclophosphamide
Cyclosporin A
Cyproheptadine
Dantrolene
Deferoxamine Mesylate
Deoxyepinephrine
Desipramine
Desmethyldiazepam
Desoximetasone
Dexamethasone
Dextromethorphan
Diazoxide
Dichloromethane
Dichlorphenamide
Diclofenac
Dicyclomine
Dieldrin
Diflorasone Diacetate
Diflucortolone pivalate
Diflunisal
Digitoxin
Digoxin
Dihydroxymandelic Acid
Theophylline
Dimenhydrinate
Dimercaprol
Dimethylaminoantipyrin
Dimethyl Isosorbide
Dimethyl Sulfoxide
Diphenhydramine
Dipyridamole
Dipyrone
Disopyramide
Dobutamine
Doxepin
Doxycycline
Doxylamine
Droperidol
Ecgonine
Ecgonine Methyl Ester
Emetine
Ephedrine
Epinephrine
Erythromycin
Eserine
Estradiol
Estriol
Estron
Glucuronide
Estrone-3-Sulfate
Ethacrynic Acid
Ethambutol
Ethamivan
Ethanol, Standard
Ethopropazine
Ethosuximide Phenylmalonamide
Ethylene Glycol
Ethylenediamine Tetraacetic Acid
Etodolac
Etoposide
Famotidine
Fenfluramine
Fenoprofen
Fentanyl
Ferrous Sulfate
Flufenamic Acid
Flunisolide
Fluphenazine
Flurandrenolide
Flurazepam
Flurbiprofen
Formaldehyde
Furosemide
Gemfibrozil
Gentamicin Sulfate
Gentisic Acid
Glucose
Glybenclamide
Griseofulvin
Guaiacol Glyceryl Ether
Guanethidine
Halcinonide
Haloperidol
Hemoglobin
Hexachlorocyclohexane
Hexachlorophene
Hexobarbital
Hippuric Acid
Histamine
DL-Homatropine
Hydrastine
Hydrochlorothiazide
Hydrocortisone
Hydrocarbalamine
Hydroflumethiazide
Hydroxyhippuric Acid
Hydroxyzine
Ibuprofen
Indapamide
Indomethacin
Ipratropium Bromide
Iproniazid
Isonicotinic Acid
Isopropamide
Isoxsuprine
Kanamycin
Ketamine
Ketoprofen
Kynurenic Acid
Labetalol
Levorphanol
Lidocaine
Lisinopril
Lithium Carbonate
Loperamide
Lormetazepam
Lysergic Acid Diethylamide (LSD)
Mebendazole
Meclizine
Meclofenamic Acid
Medazepam
Mefenamic Acid
Melanin
Melphalan
Menthol
Meperidine
Mephenesin
Mephentermine
Meprobamate
Metaproterenol
Metaraminol
Methadone
Methanol, Absolute
Methaqualone
Methazolamide
Methotrimeprazine
Methoxamine
Naphthalene Acetic Acid
Naproxen
Methoxyamine
Methoxyphenamine
Hydroxyprogesterone
Methylene Blue
Methylphenidate (Ritalin)
Methyl Salicylate
Meticrane
Metronidazole
Mianserin
Milrinone
Minaprine
Nabumetone
Nadolol
Nafcillin
Nalbuphine
Nalidixic Acid
Nalmefene
Nalorphine
Naloxone
Naltrexone
Naphazoline
Naphthalene Acetic Acid
Naphthol
Neomycin Sulfate
Niacinamide
Nialamide
(+/-) Nicotine
Nicotinic Acid
Nifedipine
Nitrofurantoin
Nomifensine
Norclomipramine
Norcocaine
Norcodeine
Nordoxepin
Norethindrone
Norfloxacin
Normorphine
Noscapine
Nylidrin
Orphenadrine
Oxalic Acid
Oxolinic Acid
Oxprenolol
Oxymetazoline
Oxyphenbutazone
Oxypurinol
Paclitaxel
Pancuronium Bromide
Papaverine
Pargyline
Penicillin
Pentachlorophenol
Pentoxifylline
Pentylenetetrazole
p-Phenylenediamine
Phenelzine
Phenformin
Pheniramine
Phenol
Phenolphthalein
Phenothiazine
Phenoxymethyl
Penicillinic acid (Penicillin V)
Phentolamine
Phenylbutazone
Phenylethylamine
Phenylpropanolamine
Phenyltoloxamine
Picrotoxin
Pilocarpine
Pimozide
Pinacidil
Pindolol
Pipecolic Acid
Pipedemic Acid
Piroxicam
Potassium Chloride
Potassium Iodide
Prazepam
Prazosin
Prednisone
Prilocaine
Primaquine
Primidone
Proadifen
Probenecid
Procainamide
Prochlorperazine
Procyclidine
Promazine
Promethazine
Propionylpromazine
Protriptyline
Pseudoephedrine
Pyridine-2-Aldoxime
Pyridoxine
Pyrilamine
Quinidine
Quinine
Quinolinic Acid
Ranitidine
Rescinnamine
Reserpine
Riboflavin
Ritodrine
Salbutamol (Albuterol)
Salicylic Acid
Sodium Chloride
Sodium Formate
Sulfamethazine
Sulfamethoxazole
Sulfanilamide
Sulfathiazole
Sulfisoxazole
Sulindac
Talbutal
Tannic Acid
Terbutaline
Terfenadine
Tetracycline
Theobromine
Theophylline
Thiamine
Thioridazine
Tobramycin
Tolazamide
Tolbutamide
Tolmetin
Toluene
Trazodone
Triamcinolone
Triamterene
Trichlormethiazide
Trichloroacetic acid
Trifluoperazine
Triflupromazine
Trimethoprim
Trimipramine
Triprolidine
Tropic Acid
Tropine
Tryptamine
Tyramine
Urea (Carbamide)
Uric Acid
Vancomycin
Vincamine
Xylometazoline
Yohimbine
Zearalenone
Zomepirac
Zopiclone

Methadone Non Cross-Reacting Compound
*Parent compound only

Acebutolol
Acetaldehyde
Acetaminophen Acetazolamide

Acetone
Acetophenetidin
N-Acetylprocainamide (Acecainide)
Acetylsalicylic Acid (Aspirin)
Aminopyrine
Amitryptyline
Ammonium Chloride
Amobarbital
Amoxicillin
Amphotericin B
Ampicillin
Aniline
Antipyrine
DL-Amphetamine sulfate
DL-Aspartic Acid
L-Aspartic Acid
Apomorphine
Aprobarbital
Aspartame
Atropine
Barbituric Acid
Benzidine
Benzilic Acid Benzocaine
Benzoic Acid
Benzoylecgonine
Benzphetamine
Benzthiazide
Bilirubin
Bisacodyl
Bromazepam
2-Bromo-a-ergocryptine
Brompheniramine
Caffeine
Cannabidiol
Cannabinol
Chloramphenicol
Chlorcyclizine
Chlordiazepoxide
Chloroquine
Chlorothiazide
Chlordiazepoxide
Chlorpheniramine
Chlorpromazine
Dimercaprol
Dimethylaminoantipyrin
Dimethyl Isosorbide
Dimethyl Sulfoxide
Disopyramide
Dobutamine
Doxepin
Doxycycline
Ecgonine
Ecgonine Methyl Ester
Emetine
Ephedrine
Epinephrine
Erythromycin
Estriol
Estrone
Ethyl-p-aminobenzoate
Etodolac
Etoposide
Famotidine
Fenfluramine
Ferrous Sulfate
Flufenamic Acid
Flunisolide
Formaldehyde
Furosemide
Gemfibrozil
Gentamicin Sulfate
Gentisic Acid
Glucose
Hemoglobin
Hydralazine
Hydrastine
Hydrochlorothiazide
Hydrocodone
Hydrocortisone
Hydrocarbalamine

Hydroflumethiazide
Hydroxyhippuric Acid
p-Hydroxyamphetamine
Hydroxyzine
Ibuprofen
Imipramine
Indapamide
Indomethacin
Ipratropium Bromide
Iproniazid
Isonicotinic Acid
Isopropamide
Isoxsuprine
Kanamycin
Ketamine
Ketoprofen
Kynurenic Acid
Labetalol
Levorphanol
Loperamide
Meperidine
Mephentermine
Methoxyphenamine
Hydroxyprogesterone
Methylphenidate (Ritalin)
Methyl Salicylate
Nabumetone
Nadolol
Nafcillin
Nalidixic Acid
Nalmefene
(+/-) Nicotine
Nicotinic Acid
Nifedipine
Nitrazepam
Noscapine
Oxycodone
Oxymetazoline
Oxyphenbutazone
Oxypurinol
Paclitaxel
Pancuronium Bromide
Papaverine
Pargyline
Penicillin
Pentachlorophenol
Pentobarbital
Pentoxifylline
Pentylenetetrazole
p-Phenylenediamine
Phenelzine
Phenformin
Pheniramine
Phenobarbital
Phenol
Phenolphthalein
Phenothiazine
Phenoxymethyl
Penicillinic acid (Penicillin V)
Phentolamine
Phenylbutazone
Phenylethylamine
Phenylpropanolamine
Phenyltoloxamine
Picrotoxin
Pilocarpine
Pimozide
Pinacidil
Pindolol
Pipecolic Acid
Pipedemic Acid
Piroxicam
Potassium Chloride
Potassium Iodide
Prazepam
Prazosin
Prednisone
Prilocaine
Primaquine
Primidone

Proadifen
Probenecid
Procainamide
Prochlorperazine
Procyclidine
Promazine
Promethazine
Propionylpromazine
Protriptyline
Pseudoephedrine
Pyridine-2-Aldoxime
Pyridoxine
Pyrilamine
Quinidine
Quinine
Quinolinic Acid
Oxazepam
Ranitidine
Rescinnamine
Reserpine
Riboflavin
Ritodrine
Salbutamol (Albuterol)
Salicylic Acid
Secobarbital
Sodium Chloride
Sodium Formate
Sulfamethazine
Sulfamethoxazole
Sulfanilamide
Sulfathiazole
Sulfisoxazole
Sulindac
Talbutal
Tamoxifen
Tannic Acid
Tenoxicam
Terbutaline
Terfenadine
Tetracycline
Tetraethylthiuram
Tetrahydrozoline
Theobromine
Theophylline
Thiamine
Thioridazine
Tobramycin
Tolazamide
Tolbutamide
Tolmetin
Toluene
Trazodone
Triamcinolone
Triamterene
Triazolam
Trichlormethiazide
Trichloroacetic acid
Trifluoperazine
Triflupromazine
Trimethobenzamide
Trimethoprim
Trimipramine
Triprolidine
Tropic Acid
Tropine
Tryptamine
Tyramine
Urea (Carbamide)
Uric Acid
Vancomycin
Vincamine
Xylometazoline
Yohimbine
Zearalenone
Zomepirac
Zopiclone

Tricyclic Antidepressants Non Cross-Reacting Compound
*Parent compound only

4-Acetamidophenol
Acetophenetidin
N-Acetylprocainamide
Acetylsalicylic acid
Aminopyrine
Amobarbital
Amoxicillin
DL-Amphetamine
Ampicillin
Ascorbic acid
Apomorphine
Aspartame
Atropine
Benzilic acid
Benzoic acid
Benzoylecgonine
Benzphetamine
Bilirubin
Brompheniramine
Caffeine
Cannabidiol
Cannabinol
Chloralhydrate
Chloramphenicol
Chlordiazepoxide
Chlorothiazide
(±) Chlorpheniramine
Chlorpromazine
Chlorquine
Cholesterol
Clonidine
Cocaine hydrochloride
Codeine
Cortisone
(-) Cotinine
Creatinine
Deoxycorticosterone
Dextromethorphan
Diazepam
Diclofenac
Diflunisal
Digoxin
Diphenhydramine
Doxylamine
Ecgonine hydrochloride
Ecgonine methylester
(1R,2S)-(-)-Ephedrine
L-Ephedrine
(-)-Ψ-Ephedrine
Erythromycin
β-Estradiol
Estrone-3-sulfate
Ethyl-p-aminobenzoate
Fenoprofen
Furosemide
Gentisic
Hemoglobin
Hydralazine
Hydrochlorothiazide
Hydrocodone
Hydrocortisone
p-Hydroxyamphetamine
O-Hydroxyhippuric
p-Hydroxy-methamphetamine
3-Hydroxytyramine
Ibuprofen
Iproniazid
(-) Isoproterenol
Isoxsuprine
Ketamine
Ketoprofen
Labetalol
Levorphanol
Loperamide
Meperidine
Meprobamate
Methadone
D-methamphetamine
Methoxyphenamine
3,4-Methylene-dioxyethylamphetamine

(+)3,4-Methylene-dioxymethamphetamine
Methylphenidate
Morphine-3-β-D-glucuronide
Morphine sulfate
Nalidixic acid
Naloxone
Naltrexone
Naproxen
Niacinamide
Nifedipine
Norcodein
Norethindrone
D-Norpropoxyphene
Noscapine
D,L-Octopamine
Oxalic acid
Oxazepam
Oxolinic acid
Oxycodone
Oxymetazoline
Papaverine
Penicillin-G
Pentazocine
Pentobarbital
Perphenazine
Phencyclidine
Phenelzine
Phenobarbital
Phentermine
Trans-2-Phenyl-cylopropylamine-hydrochloride
β-Phenylethylamine
Phenylpropanolamine
Prednisolone
Prednisone
Procaine
Promethazine
D,L-Propanolol
D-Propoxyphene
D-Pseudoephedrine
Quinidine
Quinine
Ranitidine
Salicylic acid
Secobarbital
Serotonin (5-Hydroxytyramine)
Sulfamethazine
Sulindac
Temazepam
Tetracycline
Tetrahydrocortisone, 3
Acetate
Tetrahydrocortisone 3 (β-D-glucuronide)
Tetrahydrozoline
Thiamine
Thioridazine
Tolbutamine
Triamterene
Trifluoperazine
Trimethoprim
D, L-Tryptophan
Tyramine
D, L-Tyrosine
Uric acid
Verapamil
Zomepirac

Methylenedioxymethamphetamine Non Cross-Reacting Compound
*Parent compound only

acetaldehyde
acetaminophen
acetazolamide
acetone
albumin
albuterol
ammonium
amphotericin B
ampicillin
amitriptyline
apomorphine
ascorbic acid
aspartate
aspirin
atenolol
atropine
beclomethasone
benzocaine
benzoic acid
bilirubin
bupropion
buspirone
caffeine
captopril
carbamazepine
cefaclor
cimetidine
chloramphenicol
chlordiazepoxide
chloroquine
chlorothiazide
chlorpheniramine
chlorpromazine
chlorpropamide
cholesterol
clindamycin
clonidine
clozapine
colchicine
cortisone
creatinine
deoxycorticosterone
desipramine
dextromethorphan
diazepam
digoxin
diphenhydramine
dipyridamole
doxycycline
erythromycin
estradiol
estriol
estrone
ethanol
ethylene glycol
epinepherine
ferrous sulfate
furosemide
gentamycin
glucose
haloperidol
hemoglobin
hydralazine
hydrocortisone
hydroxycarbalamine
hydroxyprogesterone
hydroxyzine
ibuprofen
indomethacin
lidocaine
lisinopril
lithium
loperamide
lorazepam
LSD
metronidazole
naproxen
niacinamide
nicotine
nifedipine
nitrofurantoin
nortriptyline
ofloxacin
oxalic acid
penicillin G
pentobarbital
phenobarbital
prednisolone
prednisone
prochloperazine
promethazine
propoxyphen
propranolol
prozac(fluoxetin)
pseudoephedrine
pyroxidine
quinidine
ranitidine
riboflavin
salicylic acid
sidenafil(viagra)
sodium chloride
sulfamethoxazole
sulindac
temazepam
tetracycline
tetrahydrocortisone
theophyline
thiamine
thioridazine
thyroxine
tolbutamide
trazodone
trimethoprim
tryptophan
tyrosine
urea
uric acid
valproic acid
verapamil
Zoloft

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Manufactured for:
W.H.P.M., Inc.
5358 Irwindale Ave.
Irwindale, CA 91706
www.whpm.com

Effective date: 06/15/2011

K2/Spice On-site Test

Now available!

Single-dip Urinalysis
K2/Spice Test

Premier Biotech is excited to offer an on-site dip test for K2 or "Spice" as one of the first screens for synthetic marijuana on the market. The K2/Spice Test is available in single strip or single dip cassette format for greater flexibility and cost effectiveness.

Test Performance

A study was conducted by a third-party lab using known positive urine from six donors. Each specimen was screened with the K2/Spice Test. The laboratory then processed and tested each specimen following forensic guidelines.

	JWH-018 Pentanoic Acid			JWH-073 Butanoic Acid		
Donor	K2/ Spice Test	Lab confir-mation	Result (µg/ml)	K2/ Spice Test	Lab confir-mation	Result (µg/ml)
1	Positive	Positive	1.5	Negative	-	-
2	Positive	Positive	65.2	Positive	Positive	2.3
3	Positive	Positive	107.1	Positive	Positive	7.0
4	Positive	Positive	116.4	Positive	Positive	3.3
5	Positive	Positive	269.8	Positive	Positive	6.8
6	Positive	Positive	396.4	Positive	Positive	20.4

A precision study was performed by three individuals observing test results to determine the random error of visual interpretation. The test results were found to have no significant differences among the three observers.

K2/Spice Test	Con-trol Con. ng/ml	No. of Tested	No. of positive 1	2	3	No. of borderline 1	2	3	No. of negative 1	2	3
JWH-018 and JWH-073	0	42							42	42	42
	25	42							42	42	42
	75	42	40	41	40	2	1	2			

Specific to JWH-018 pentanoic acid and JWH-073 butanoic acid

Compounds	*Concentration*	*Cross reactivity*
JWH-018 pentanoic acid	*50 ng/ml*	*100%*
JWH-073 butanoic acid	*50 ng/ml*	*100%*

FORENSIC USE ONLY

888-686-9909 | premierbiotech.com
6630 Lakeway Drive, Chanhassen MN 55317

K2 or "Spice" is an illicit drug that is comprised of a mixture of herbs and spices, typically sprayed with a synthetic compound that is chemically similar to THC, the psychoactive ingredient in marijuana. The most common chemical compounds of K2 include HU-210, HU-211, JWH-018, and JWH-073. K2 is often marketed in head shops, tobacco shops, or over the Internet as incense or "fake weed." Unknown product origin and amount of chemical compound on the organic material are just two of the many risks associated with K2/Spice.

Street names

Bliss, Black Mamba, Bombay Blue, Cloud Nine, Fake Weed, Genie, Spice, Zohai

Looks like

K2 is typically sold in small, silvery plastic bags of dried leaves and marketed as incense that can be smoked. It is said to resemble potpourri.

Methods of abuse

K2 products are usually smoked in joints or pipes, but some users make it into a tea.

Affect on mind

Psychological effects are similar to those of marijuana and include paranoia, panic attacks, and giddiness.

Affect on body

Physiological effects of K2 include increased heart rate and increase of blood pressure. It appears to be stored in the body for long periods of time, and therefore the long-term effects on humans are not fully known.

Drugs causing similar effects

Marijuana

Overdose effects

There have been no reported deaths by overdose.

Legal status in the United States

On Tuesday, March 1, 2011, DEA published a final order in the Federal Register temporarily placing five synthetic cannabinoids into Schedule I of the CSA. The order became effective on March 1, 2011. The substances placed into Schedule I are 1-pentyl-3-(1-naphthoyl) indole (JWH-018), 1-butyl-3-(1-naphthoyl) indole (JWH-073), 1-[2-(4-morpholinyl) ethyl]-3-(1-naphthoyl)indole (JWH-200), 5-(1,1-dimethylheptyl)-2-[(1R,3S)-3-hydroxycyclohexyl]-phenol (CP-47,497), and 5-(1,1-dimethyloctyl)-2-[(1R,3S)-3-hydroxycyclohexyl]-phenol (cannabicyclohexanol; CP-47,497 C8 homologue). This action is based on a finding by the Administrator that the placement of these synthetic cannabinoids into Schedule I of the CSA is necessary to avoid an imminent hazard to the public safety. As a result of this order, the full effect of the CSA and its implementing regulations including criminal, civil and administrative penalties, sanctions, and regulatory controls of Schedule I substances will be imposed on the manufacture, distribution, possession, importation, and exportation of these synthetic cannabinoids.

Common places of origin

Manufacturers of this product are not regulated and are often unknown since these products are purchased via the Internet whether wholesale or retail. Several websites that sell the product are based in China. Some products may contain an herb called damiana, which is native to Central America, Mexico, and the Caribbean.

Source: dea.gov – "Drug Fact Sheet: K2 or Spice"

DRUGS TESTS AVAILABLE IN DIP CASSETTE OR SINGLE STRIPS

URINALYSIS CUTOFFS	
Alcohol (ALC)	.04%*
Amphetamine (AMP)	1,000 500* 300*
Barbiturates (BAR)	300
Benzodiazepines (BZO)	300 200*
Buprenorphine (BUP)	10 5*
Cocaine (COC)	300 150
Cotinine (COT)	200*
EDDP	100*
Fentanyl (FYL)	200*
Ketamine (KET)	1,000*
K2/Spice	50*
Marijuana (THC)	300* 50 25*
Methadone (MTD)	300
Methamphetamine (MET)	1,000 500 300*
Methylenedioxymeth-amphetamine (MDMA)	500
Opiates (OPI)	2,000 300
Oxycodone (OXY)	100
Phencyclidine (PCP)	25
Propoxyphene (PPX)	300
Tramadol (TML)	100*
Tricyclic Antidepressants (TCA)	1,000

** FORENSIC USE ONLY*
All cutoffs in ng/mL except alcohol

Premier BIOTECH

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