OneStep+ Drugs of Abuse Cup DRUG PANEL WITH ADULTERANTS Step by Step Instructions

For in vitro diagnostic use. Product may be used by laboratories with a CLIA Certificate of Waiver.

The OneStep+ Drugs of Abuse Cup is a screening test for the rapid qualitative detection of multiple drugs and/or drug metabolites in human urine at or above the following cutoff concentrations:

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

This test provides visual qualitative results and is intended for over-the-counter and prescription point-of-care use. The OneStep+ Drugs of Abuse Cup is available in multiple drug analyte combinations.

This test provides only preliminary results and is the first step in a two-step process for identifying drugs in urine. The second step is confirming the results at a certified laboratory. To confirm preliminary positive results obtained by the OneStep+ Drugs of Abuse Cup, a more specific alternative method such as Gas Chromatography-Mass Spectrometry (GC-MS) or Liquid Chromatography-Tandem Mass Spectrometry (LC-MS/MS) must be used. Clinical consideration and professional judgment must be applied to any drug test result, particularly when a preliminary positive result is indicated.

TESTING MATERIALS

The following materials are for testing an individual urine sample. Kits may contain supplies for testing 1 to 25 urine samples.					
 ✓ Step-by-Step Test Instructions ✓ Individually Wrapped Test Lid ✓ Specimen Cup 	Specimen Collection Cup	And the second s	Individually Wrapped Test Lid		

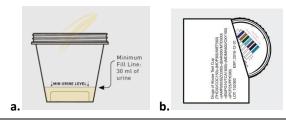
STORAGE

Store the OneStep+ Drugs of Abuse Cup at room temperature 59°F to 86°F (15°C to 30°C).

INSTRUCTIONS

Step 1.

- a. Collect fresh urine in the specimen cup.
 Make sure the urine is above the minimum fill line.
- b. Open foil pouch. Remove test lid from pouch. Discard desiccant.



Step 2.

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

IMPORTANT: Cup lid must be secured tightly by twisting it a quarter turn AFTER lid is snug.



Step 3.

Tilt the cup on its legs to activate the test.

Read test results at 5 minutes. Do not read after 8 minutes.



INTERPRETATION OF RESULTS

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

For C region:

The appearance of a colored line indicates a valid result.

No colored line means an **Invalid** result. If a test strip does not have a colored line in the C region, test results are **Invalid** for both T1 and T2 on that strip.

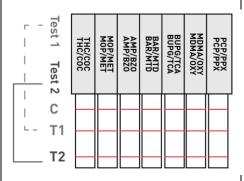
For T1 and T2 regions:

The appearance of a colored line indicates a **Negative** result. Note: **Any colored test line, even a faint colored test line, is considered a negative result.**

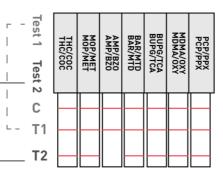
No colored line indicates a **Preliminary Positive** result.

Note: Any urine with preliminary positive results should be sent to a laboratory for confirmation.

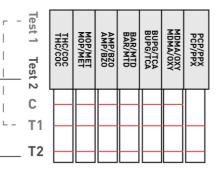
Test 1 Test 2	THC/COC	MOP/MET	AMP/BZO	BAR/MTD	BUPG/TCA	MDMA/OXY	PCP/PPX	Test 1 row for: THC, MOP, AMP, BAR, BUPG, MDMA, PCP
	THC/COC	MOP/MET	AMP/BZO	BAR/MTD	BUPG/TCA	MDMA/OXY	PCP/PPX	Test 2 row for: COC, MET, BZO, MTD, TCA, OXY, PPX
C T1 T2								 C region: shows validity for each strip T1 region: shows results for Test 1 on each strip T2 region: shows results for Test 2 on each strip



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



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



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

DETECTION LEVELS AND APPROXIMATE DETECTION TIMES

Drug	Test Identifier	Cut-off Level ¹	Minimum Detection Time ²	Maximum Detection Time ²
Marijuana	THC	50 ng/ml	1-3 hours	1-7 days
Cocaine	COC	150 ng/ml	2-6 hours	2-3 days
Opiates	MOP	300 ng/ml	2-6 hours	1-3 days
Methamphetamine	MET	500 ng/ml	4-6 hours	2-3 days
Amphetamine	AMP	500 ng/ml	4-6 hours	2-3 days
Ecstasy	MDMA	500 ng/ml	2-7 hours	2-4 days
Phencyclidine	РСР	25 ng/ml	4-6 hours	7-14 days
Propoxyphene	РРХ	300 ng/ml	2-8 hours	2-7 days
Benzodiazepines	BZO	300 ng/ml	2-7 hours	1-4 days
Barbiturates	BAR	300 ng/ml	2-4 hours	1-3 weeks
Methadone	MTD	300 ng/ml	3-8 hours	1-3 days
Buprenorphine	BUPG	10 ng/ml	2-7 hours	1-6 days
Tricyclic Antidepressants	TCA	1000 ng/ml	8-12 hours	2-7 days
Oxycodone	OXY	100 ng/ml	1-3 hours	1-2 days

 1 Cut-off level is the lowest drug concentration in the urine that can be detected by the OneStep+ Drugs of Abuse Cup .

² Drug clearance rates are dependent on many factors such as frequency of drug use, the amount of drug taken, metabolism rates, and even body fat content.

CONFIRMATION TESTING ITEMS

The following materials may be used to send an individual urine sample to a laboratory for confirmation testing. These items are included in over-the-counter kits.

✓ 1 Specimen Bag		Image: Description of the sector of the s	
 ✓ 2 Identification Labels 		COC MET BZO MTD TCA OXY PPX	Mailing Label
 ✓ 1 Mailing Label 		ID#: DT14-XXXXX-XXXX	
	Specimen Bag	Identification Label	

PROCEDURE FOR CONFIRMATION

The following procedure may be used for confirming preliminary positive results:

Step 1:

Make sure the lid is twisted tightly. Place a check mark in the box on both Identification Labels for the drug(s) with preliminary positive result. Place one Identification Label onto the OneStep+ Drugs of Abuse Cup. Place the other Identification Label below for your record. You will need this identification number to access the confirmation result.

Place Identification Label Here

Step 2:

Place the labeled OneStep+ Drugs of Abuse Cup into the Specimen Bag and seal the bag.

Step 3:

Place specimen into a shipping box and affix the Mailing Label. Drop the shipping box with POSTAGE into any mailbox. Specimen should be mailed within 24 hours of collection.

Step 4:

Obtain confirmation results:

- Results will be ready in 5 to 7 days after the sample is received in our laboratory (time for results may vary if using another laboratory).
- Call 1-800-472-4346 to obtain confirmation result (for over-the-counter kit).
- You will need the identification number to access the confirmation result.

WARNINGS AND PRECAUTIONS

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

UNDERSTANDING THE TEST RESULTS & FOLLOW UP

What is a Preliminary Positive Result?

The OneStep+ Drugs of Abuse Cup is a screening test to detect the presence of drugs in human urine. This means that if a drug is present, you will usually get a preliminary positive test result. It is important to send out the specimen to confirm the preliminary positive result. This is because certain foods, supplements, beverages, or medicines can affect the results of the OneStep+ Drugs of Abuse Cup.

If the test results are preliminary positive, does it mean that you found drugs of abuse?

No. Take no serious actions until you get the laboratory's result. Many factors may cause a false positive result in the screening test. A positive test for a prescription drug does not mean that a person is abusing the drug. This is because the test does not indicate acceptable levels compared to abusive levels of prescribed drugs. This test cannot be used for legal purposes. If you get a preliminary positive test result, you should send the urine to a laboratory to confirm the test result. The confirmation test is called gas chromatography-mass spectrometry (or GC-MS) or liquid chromatography-tandem mass spectrometry (LC-MS/MS).

Many things can affect the accuracy of the tests, including (but not limited to):

- The way you did the test.
- The way you stored the test or urine.
- What the person ate or drank before taking the test.
- Any other prescription or over-the-counter drugs the person may have taken before the test.
- Note: Some over-the-counter medications will produce the same test results as illegally-abused amphetamines.

Where can I get some help?

Consult with a counselor, doctor, or a qualified professional to help you address drug abuse problems. The following organizations provide helpful resources on drug abuse prevention and recovery programs. These resources are for information purposes only.

Alcohol and Drug Information <u>http://store.samhsa.gov/home</u> Community Anti-Drug Coalitions of America <u>http://www.cadca.org</u> National Institute on Drug Abuse <u>http://www.drugabuse.gov</u>.

LIMITATIONS OF THE TEST

- The assay is designed for use with human urine only.
- Positive results indicate the presence of drug/metabolites only and do not indicate or measure intoxication.
- There is a possibility that technical or procedural errors as well as other substances in certain foods and medication may interfere with the test and cause false results. See the Specificity section for a list of substances that may produce positive results, and the Interference section for a list of compounds that were tested and did not interfere with the test.
- A positive drug result does not indicate the frequency or time of drug use, nor does it distinguish between drugs and certain foods and/or medications.
- If it is suspected that the sample may have been mislabeled, a new specimen should be collected.
- If it is suspected that the sample may have been tampered with, a new specimen should be collected.

PROFESSIONAL KIT CONTENTS

- 1 Step-by-Step Test Instructions
- 25 Individually Wrapped Test Lids
- 25 Specimen Cups
- 25 Tamper-evident seals

TEST PRINCIPLE

The OneStep+ Drugs of Abuse Cup is based on the principle of the highly specific immunochemical reactions between antigens and antibodies, which are used for the analysis of specific substances in urine. The test is based on a competitive immunoassay procedure in which immobilized drug conjugates compete with the drug(s) present in urine for limited binding sites of the antibody conjugated to colloidal gold. If there is drug or drug metabolite in the urine sample, the binding sites of the antibody-colloidal gold conjugate cannot bind to the specific test region. The absence of a color band indicates a positive result for that particular test. If there is no drug or drug metabolite present to compete for the binding sites of the colored colloidal gold conjugate, a visible color band forms at the specific test region indicating a negative result for that particular test. A control band with a different antigen/antibody reaction should always appear regardless of the presence of drug or metabolite.

SPECIMEN COLLECTION AND HANDLING

Fresh urine does not require any special handling or pretreatment. A fresh urine sample should be collected in the specimen container provided. Urine samples should be tested as soon as possible after collection, preferably within the same day. Specimens that have been refrigerated or frozen must be brought to room temperature and mixed thoroughly prior to testing.

Note: All materials coming into contact with urine specimens should be handled and disposed of as if potentially infectious. Avoid direct contact and follow good laboratory practice.

QUALITY CONTROL

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

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

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

PERFORMANCE CHARACTERISTICS

PRECISION

A study was conducted at two laboratories and one physician office in an effort to determine the precision of the OneStep+ Drugs of Abuse Cup over 12 or more consecutive days. Testing was conducted on the Amphetamine, Barbiturates, Benzodiazepines, Buprenorphine, Cocaine, Marijuana, Methamphetamine, Methylenedioxymethamphetamine,

Methadone, Opiates, Oxycodone, Phencyclidine, Propoxyphene, and Tricyclic Antidepressants assays by operators using three different lots of product to demonstrate the within-run, between-run and between-operator precision. An identical panel of coded samples, containing drugs at the concentration of \pm 50% cut-off level was labeled as a blind and tested at each site. The correlation with expected results was >99% across all lots and sites (with a 95% confidence interval).

ACCURACY

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

Drug Test		GC-MS Neg.	GC-MS	GC-MS -50% to	GC-MS Cutoff to	GC-MS	0	ment w/ ·MS
			< -50%	Cutoff	+50%	> +50%	Neg (-)	Pos (+)
ТНС 50	Pos. (+)	0	0	1	6	35	97.7%	100%
	Neg. (-)	36	2	4	0	0	57.770	100%
сос	Pos. (+)	0	0	3	3	37	92.7%	97.6%
150	Neg. (-)	36	0	2	1	0	92.7%	
МОР	Pos. (+)	0	0	3	7	34	92.5%	100%
300	Neg. (-)	36	0	1	0	0		100%
MET	Pos. (+)	0	0	0	5	67	100%	96.0%
500	Neg. (-)	36	2	4	3	0	100%	90.0%
AMP	Pos. (+)	0	0	2	5	36	95.1%	100%
500	Neg. (-)	36	1	2	0	0	95.1%	
BZO	Pos. (+)	0	0	3	4	39	92.5%	100%
300	Neg. (-)	36	0	1	0	0	92.5%	100%
BAR	Pos. (+)	0	0	1	6	33	97.5%	95.1%
300	Neg. (-)	36	0	3	2	0		
MTD	Pos. (+)	0	0	0	3	36	100%	07.5%
300	Neg. (-)	36	0	4	1	0		97.5%
BUPG	Pos. (+)	0	0	1	4	38	97.5%	97.7%
10	Neg. (-)	36	0	3	1	0	97.5%	97.7%
TCA	Pos. (+)	0	0	0	27	11	100%	92.7%
1000	Neg. (-)	36	0	4	3	0	100%	92.7%
MDMA	Pos. (+)	0	0	1	3	40	97.5%	97.7%
500	Neg. (-)	36	0	3	1	0	97.5%	97.7%
OXY	Pos. (+)	0	0	2	6	38	05.2%	100%
100	Neg. (-)	36	0	4	0	0	95.2%	100%
РСР	Pos. (+)	0	0	0	3	36	100%	OF 19/
25	Neg. (-)	36	0	4	2	0	100%	95.1%
РРХ	Pos. (+)	0	0	2	4	36	05.0%	100%
300	Neg. (-)	36	0	2	0	0	95.0%	100%

SPECIFICITY

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

The following compounds produced positive results when tested at or above the concentrations listed below. The calibrator for each test is marked with an asterisk (*).

AMP 500 ng/ml

AMP 500 ng/ml			
Compound	ng/ml	Compound	ng/ml
d-Amphetamine *	500	Phentermine	1,000
l-Amphetamine	20,000	β-Phenylethylamine	80,000
d,I-3,4-MDA	1,500		
BAR 300 ng/ml			
Compound	ng/ml	Compound	ng/ml
Allobarbital	1,500	Butalbital	300
Alphenal	400	Butethal	400
Amobarbital	1,500	Pentobarbital	400
Aprobarbital	400	Phenobarbital	400
Barbital	400	Secobarbital *	300
Butabarbital	400		
BZO 300 ng/ml			
Compound	ng/ml	Compound	ng/n
α-Hydroxy Alprazolam	50	Lorazepam	1,50
Alprazolam	150	Lormetazepam	1,00
Bromazepam	800	Medazepam	2,00
Chlordiazepoxide	2,000	Nitrazepam	1,00
Clobazam	2,000	Nordiazepam	1,00
Clonazepam	4,000	Oxazepam *	30
Delorazepam	4,000 6,000	Phenazepam	1,00
Diazepam	150	Prazepam	1,00
Estazolam	300	Temazepam	1,00
Flunitrazepam	1,000	Triazolam	1,50
Flurazepam	300		1,50
	000		
BUPG 10ng/ml	in a linal	Compound	
Compound	ng/ml	Compound	ng/r
Buprenorphine Buprenorphine Glucuronide *	100 10	Norbuprenorphine Norbuprenorphine Glucuronide	10 10
Buprenorphine Glucuronide	10	Norbuprenorphine Glucuronide	п
COC 150 ng/ml			
Compound	ng/ml	Compound	ng/ml
Benzoylecgonine *	150	Ecgonine	65,000
		•	
MDMA 500 ng/ml		•	
-	ng/ml	Compound	ng/ml
Compound	ng/ml 2,000	Compound d,l-3,4-MDMA*	ng/ml 500
Compound d,I-3,4-MDA		Compound	
Compound d,I-3,4-MDA d,I-3,4-MDEA	2,000	Compound d,l-3,4-MDMA*	500
Compound d,I-3,4-MDA d,I-3,4-MDEA MET 500 ng/ml	2,000	Compound d,l-3,4-MDMA*	500
Compound d,I-3,4-MDA d,I-3,4-MDEA MET 500 ng/ml Compound	2,000 250	Compound d,I-3,4-MDMA* d-Methamphetamine	500 50,000
Compound d,I-3,4-MDA d,I-3,4-MDEA MET 500 ng/ml Compound Ephedrine	2,000 250 ng/ml	Compound d,I-3,4-MDMA* d-Methamphetamine Compound	500 50,000 ng/ml
Compound d,I-3,4-MDA d,I-3,4-MDEA MET 500 ng/ml Compound Ephedrine p-Hydroxymethamphetamine	2,000 250 ng/ml 10,000	Compound d,I-3,4-MDMA* d-Methamphetamine Compound d-Methamphetamine *	500 50,000 ng/ml 500
Compound d,I-3,4-MDA d,I-3,4-MDEA MET 500 ng/ml Compound Ephedrine p-Hydroxymethamphetamine d,I-3,4-MDMA	2,000 250 ng/ml 10,000 1,750	Compound d,I-3,4-MDMA* d-Methamphetamine Compound d-Methamphetamine * I-Methamphetamine	500 50,000 ng/ml 500 25,000
Compound d,I-3,4-MDA d,I-3,4-MDEA MET 500 ng/ml Compound Ephedrine p-Hydroxymethamphetamine d,I-3,4-MDMA d,I-3,4-MDEA	2,000 250 ng/ml 10,000 1,750 1,000	Compound d,I-3,4-MDMA* d-Methamphetamine Compound d-Methamphetamine * I-Methamphetamine Procaine	500 50,000 ng/ml 500 25,000 50,000
Compound d,I-3,4-MDA d,I-3,4-MDEA MET 500 ng/ml Compound Ephedrine p-Hydroxymethamphetamine d,I-3,4-MDMA d,I-3,4-MDEA MTD 300 ng/ml	2,000 250 ng/ml 10,000 1,750 1,000 20,000	Compound d,I-3,4-MDMA* d-Methamphetamine Compound d-Methamphetamine * I-Methamphetamine Procaine Trimethobenzamide	500 50,000 ng/ml 500 25,000 50,000 75,000
Compound d,I-3,4-MDA d,I-3,4-MDEA MET 500 ng/ml Compound Ephedrine p-Hydroxymethamphetamine d,I-3,4-MDMA d,I-3,4-MDEA MTD 300 ng/ml Compound	2,000 250 10,000 1,750 1,000 20,000 ng/ml	Compound d,I-3,4-MDMA* d-Methamphetamine Compound d-Methamphetamine * I-Methamphetamine Procaine Trimethobenzamide Compound	500 50,000 ng/ml 500 25,000 50,000 75,000 ng/ml
Compound d,I-3,4-MDA d,I-3,4-MDEA MET 500 ng/ml Compound Ephedrine p-Hydroxymethamphetamine d,I-3,4-MDMA d,I-3,4-MDEA MTD 300 ng/ml Compound Doxylamine	2,000 250 ng/ml 10,000 1,750 1,000 20,000	Compound d,I-3,4-MDMA* d-Methamphetamine Compound d-Methamphetamine * I-Methamphetamine Procaine Trimethobenzamide Compound Methadone *	500 50,000 ng/ml 5000 25,000 75,000 ng/ml 300
Compound d,I-3,4-MDA d,I-3,4-MDEA MET 500 ng/ml Compound Ephedrine p-Hydroxymethamphetamine d,I-3,4-MDMA d,I-3,4-MDEA MTD 300 ng/ml Compound Doxylamine 2-Ethylidene-1,5-Dimethyl-	2,000 250 ng/ml 10,000 1,750 1,000 20,000 ng/ml 50,000	Compound d,I-3,4-MDMA* d-Methamphetamine Compound d-Methamphetamine * I-Methamphetamine Procaine Trimethobenzamide Compound	500 50,000 ng/ml 500 25,000 50,000 75,000 ng/ml
Compound d,I-3,4-MDA d,I-3,4-MDEA MET 500 ng/ml Compound Ephedrine p-Hydroxymethamphetamine d,I-3,4-MDMA d,I-3,4-MDEA MTD 300 ng/ml Compound Doxylamine 2-Ethylidene-1,5-Dimethyl- 1-3,3-Diphenylpyrolidine	2,000 250 10,000 1,750 1,000 20,000 ng/ml	Compound d,I-3,4-MDMA* d-Methamphetamine Compound d-Methamphetamine * I-Methamphetamine Procaine Trimethobenzamide Compound Methadone *	500 50,000 ng/ml 5000 25,000 75,000 ng/ml 300
Compound d,I-3,4-MDA d,I-3,4-MDEA MET 500 ng/ml Compound Ephedrine p-Hydroxymethamphetamine d,I-3,4-MDMA d,I-3,4-MDEA MTD 300 ng/ml Compound Doxylamine 2-Ethylidene-1,5-Dimethyl- 1-3,3-Diphenylpyrolidine MOP 300 ng/ml	2,000 250 ng/ml 10,000 1,750 1,000 20,000 ng/ml 50,000	Compound d,I-3,4-MDMA* d-Methamphetamine Compound d-Methamphetamine * I-Methamphetamine Procaine Trimethobenzamide Compound Methadone * Pheniramine	500 50,000 25,000 50,000 75,000 ng/ml 300 75,000
Compound d,I-3,4-MDA d,I-3,4-MDEA MET 500 ng/ml Compound Ephedrine p-Hydroxymethamphetamine d,I-3,4-MDMA d,I-3,4-MDEA MTD 300 ng/ml Compound Doxylamine 2-Ethylidene-1,5-Dimethyl- 1-3,3-Diphenylpyrolidine MOP 300 ng/ml Compound	2,000 250 ng/ml 10,000 1,750 1,000 20,000 ng/ml 50,000 50,000 ng/ml	Compound d,l-3,4-MDMA* d-Methamphetamine Compound d-Methamphetamine * I-Methamphetamine Procaine Trimethobenzamide Compound Methadone * Pheniramine Compound	500 50,000 25,000 50,000 75,000 ng/ml 300 75,000
Compound d,I-3,4-MDA d,I-3,4-MDEA MET 500 ng/ml Compound Ephedrine p-Hydroxymethamphetamine d,I-3,4-MDMA d,I-3,4-MDEA MTD 300 ng/ml Compound Doxylamine 2-Ethylidene-1,5-Dimethyl- 1-3,3-Diphenylpyrolidine MOP 300 ng/ml Compound 6-Acetylmorphine	2,000 250 ng/ml 10,000 1,750 1,000 20,000 ng/ml 50,000 50,000 ng/ml 500	Compound d,I-3,4-MDMA* d-Methamphetamine Compound d-Methamphetamine * I-Methamphetamine Procaine Trimethobenzamide Compound Methadone * Pheniramine Compound Hydrocodone	500 50,000 ng/ml 500 25,000 75,000 ng/ml 300 75,000 ng/ml 1,000
Compound d,I-3,4-MDA d,I-3,4-MDEA MET 500 ng/ml Compound Ephedrine p-Hydroxymethamphetamine d,I-3,4-MDMA d,I-3,4-MDEA MTD 300 ng/ml Compound Doxylamine 2-Ethylidene-1,5-Dimethyl- 1-3,3-Diphenylpyrolidine MOP 300 ng/ml Compound 6-Acetylmorphine 6-Acetylcodeine	2,000 250 ng/ml 10,000 1,750 1,000 20,000 ng/ml 50,000 50,000 ng/ml 500 600	Compound d,I-3,4-MDMA* d-Methamphetamine Compound d-Methamphetamine * I-Methamphetamine Procaine Trimethobenzamide Compound Methadone * Pheniramine Compound Hydrocodone Hydrocodone	500 50,000 25,000 50,000 75,000 75,000 75,000 ng/ml 1,000 400
Compound d,I-3,4-MDA d,I-3,4-MDEA MET 500 ng/ml Compound Ephedrine p-Hydroxymethamphetamine d,I-3,4-MDMA d,I-3,4-MDEA MTD 300 ng/ml Compound Doxylamine 2-Ethylidene-1,5-Dimethyl- 1-3,3-Diphenylpyrolidine MOP 300 ng/ml Compound 6-Acetylcodeine 6-Acetylcodeine Codeine	2,000 250 ng/ml 10,000 1,750 1,000 20,000 20,000 ng/ml 50,000 50,000 ng/ml 500 600 300	Compound d,I-3,4-MDMA* d-Methamphetamine Compound d-Methamphetamine * I-Methamphetamine Procaine Trimethobenzamide Compound Methadone * Pheniramine Compound Hydrocodone Hydrocodone Hydromorphone Morphine *	500 50,000 25,000 50,000 75,000 75,000 75,000 ng/ml 1,000 400 300
Compound d,I-3,4-MDA d,I-3,4-MDEA MET 500 ng/ml Compound Ephedrine p-Hydroxymethamphetamine d,I-3,4-MDMA d,I-3,4-MDMA d,I-3,4-MDEA MTD 300 ng/ml Compound Doxylamine 2-Ethylidene-1,5-Dimethyl- 1-3,3-Diphenylpyrolidine MOP 300 ng/ml Compound 6-Acetylmorphine 6-Acetylcodeine Codeine Dihydrocodeine	2,000 250 ng/ml 10,000 1,750 1,000 20,000 20,000 50,000 50,000 50,000 ng/ml 500 600 300 500	Compound d,I-3,4-MDMA* d-Methamphetamine Compound d-Methamphetamine * I-Methamphetamine Procaine Trimethobenzamide Compound Methadone * Pheniramine Compound Hydrocodone Hydrocodone Hydromorphone Morphine * Morphine-3-β-D-Glucuronide	500 50,000 25,000 50,000 75,000 ng/ml 300 75,000 ng/ml 1,000 400 300 500
Compound d,I-3,4-MDA d,I-3,4-MDEA MET 500 ng/ml Compound Ephedrine p-Hydroxymethamphetamine d,I-3,4-MDMA d,I-3,4-MDMA d,I-3,4-MDEA MTD 300 ng/ml Compound Doxylamine 2-Ethylidene-1,5-Dimethyl- 1-3,3-Diphenylpyrolidine MOP 300 ng/ml Compound 6-Acetylcodeine Codeine Dihydrocodeine Ethyl morphine	2,000 250 ng/ml 10,000 1,750 1,000 20,000 20,000 50,000 50,000 50,000 50,000 600 300 500 300	Compound d,I-3,4-MDMA* d-Methamphetamine Compound d-Methamphetamine * I-Methamphetamine Procaine Trimethobenzamide Compound Methadone * Pheniramine Compound Hydrocodone Hydrocodone Hydromorphone Morphine *	500 50,000 25,000 50,000 75,000 ng/ml 300 75,000 ng/ml 1,000 400 300 500
Compound d,I-3,4-MDA d,I-3,4-MDEA MET 500 ng/ml Compound Ephedrine p-Hydroxymethamphetamine d,I-3,4-MDMA d,I-3,4-MDMA d,I-3,4-MDEA MTD 300 ng/ml Compound Doxylamine 2-Ethylidene-1,5-Dimethyl- 1-3,3-Diphenylpyrolidine MOP 300 ng/ml Compound 6-Acetylcodeine Codeine Dihydrocodeine Ethyl morphine	2,000 250 ng/ml 10,000 1,750 1,000 20,000 20,000 50,000 50,000 50,000 ng/ml 500 600 300 500	Compound d,I-3,4-MDMA* d-Methamphetamine Compound d-Methamphetamine * I-Methamphetamine Procaine Trimethobenzamide Compound Methadone * Pheniramine Compound Hydrocodone Hydrocodone Hydromorphone Morphine * Morphine-3-β-D-Glucuronide	500 50,000 25,000 50,000 75,000 ng/ml 300 75,000 ng/ml 1,000 400 300 500
Compound d,I-3,4-MDA d,I-3,4-MDEA MET 500 ng/ml Compound Ephedrine p-Hydroxymethamphetamine d,I-3,4-MDMA d,I-3,4-MDMA d,I-3,4-MDEA MTD 300 ng/ml Compound Doxylamine 2-Ethylidene-1,5-Dimethyl- 1-3,3-Diphenylpyrolidine MOP 300 ng/ml Compound 6-Acetylmorphine 6-Acetylcodeine Codeine Dihydrocodeine Ethyl morphine Heroin	2,000 250 ng/ml 10,000 1,750 1,000 20,000 20,000 50,000 50,000 50,000 50,000 600 300 500 300	Compound d,I-3,4-MDMA* d-Methamphetamine Compound d-Methamphetamine * I-Methamphetamine Procaine Trimethobenzamide Compound Methadone * Pheniramine Compound Hydrocodone Hydrocodone Hydromorphone Morphine * Morphine-3-β-D-Glucuronide	500 50,000 25,000 50,000 75,000 ng/ml 300 75,000 ng/ml 1,000 400 300 500
Compound d,I-3,4-MDA d,I-3,4-MDEA MET 500 ng/ml Compound Ephedrine p-Hydroxymethamphetamine d,I-3,4-MDMA d,I-3,4-MDMA d,I-3,4-MDEA MTD 300 ng/ml Compound Doxylamine 2-Ethylidene-1,5-Dimethyl- 1-3,3-Diphenylpyrolidine MOP 300 ng/ml Compound 6-Acetylmorphine 6-Acetylcodeine Codeine Dihydrocodeine Ethyl morphine Heroin	2,000 250 ng/ml 10,000 1,750 1,000 20,000 20,000 50,000 50,000 50,000 50,000 600 300 500 300	Compound d,I-3,4-MDMA* d-Methamphetamine Compound d-Methamphetamine * I-Methamphetamine Procaine Trimethobenzamide Compound Methadone * Pheniramine Compound Hydrocodone Hydrocodone Hydromorphone Morphine * Morphine-3-β-D-Glucuronide	500 50,000 ng/ml 500 25,000 75,000 ng/ml 300 75,000 ng/ml 1,000 400 300 5,000
Compound d,I-3,4-MDA d,I-3,4-MDEA MET 500 ng/ml Compound Ephedrine p-Hydroxymethamphetamine d,I-3,4-MDMA d,I-3,4-MDMA d,I-3,4-MDEA MTD 300 ng/ml Compound Doxylamine 2-Ethylidene-1,5-Dimethyl- 1-3,3-Diphenylpyrolidine MOP 300 ng/ml Compound 6-Acetylcodeine Ethyl morphine Heroin OXY 100 ng/ml Compound 6-Acetylcodeine	2,000 250 ng/ml 10,000 1,750 1,000 20,000 20,000 50,000 50,000 50,000 50,000 50,000 100 100 ng/ml 15,000	Compound d,I-3,4-MDMA* d-Methamphetamine Compound d-Methamphetamine * I-Methamphetamine Procaine Trimethobenzamide Compound Methadone * Pheniramine Compound Hydrocodone Hydrocodone Hydromorphone Morphine * Morphine-3-β-D-Glucuronide Nalorphine	500 50,000 ng/ml 500 25,000 75,000 75,000 ng/ml 1,000 4000 500 5,000 5,000
Compound d,I-3,4-MDA d,I-3,4-MDEA MET 500 ng/ml Compound Ephedrine p-Hydroxymethamphetamine d,I-3,4-MDMA d,I-3,4-MDMA d,I-3,4-MDEA MTD 300 ng/ml Compound MOP 300 ng/ml Compound 6-Acetylcodeine Ethyl morphine Heroin OXY 100 ng/ml Compound 6-Acetylcodeine Compound 6-Acetylcodeine Compound	2,000 250 ng/ml 10,000 1,750 1,000 20,000 20,000 50,000 50,000 50,000 50,000 500 300 500 300 500 300 100 15,000 5,000	Compound d,I-3,4-MDMA* d-Methamphetamine Compound d-Methamphetamine * I-Methamphetamine Procaine Trimethobenzamide Compound Methadone * Pheniramine Compound Hydrocodone Hydrocodone Morphine * Morphine 3-β-D-Glucuronide Nalorphine Compound	500 50,000 25,000 50,000 75,000 75,000 75,000 75,000 75,000 1,000 5,000 5,000 5,000
Compound d,I-3,4-MDA d,I-3,4-MDEA MET 500 ng/ml Compound Ephedrine p-Hydroxymethamphetamine d,I-3,4-MDMA d,I-3,4-MDMA d,I-3,4-MDEA MTD 300 ng/ml Compound Compound MOP 300 ng/ml Compound 6-Acetylcodeine Ethyl morphine Heroin OXY 100 ng/ml Compound 6-Acetylcodeine Ethyl morphine Heroin OXY 100 ng/ml Compound 6-Acetylcodeine Codeine Dihydrocodeine Ethyl morphine Heroin	2,000 250 ng/ml 10,000 1,750 1,000 20,000 20,000 50,000 50,000 50,000 500 300 500 300 500 300 100 15,000 5,000 2,000	Compound d,I-3,4-MDMA* d-Methamphetamine Compound d-Methamphetamine * I-Methamphetamine * I-Methamphetamine Procaine Trimethobenzamide Compound Methadone * Pheniramine Compound Hydrocodone Hydrocodone Hydromorphone Morphine * Morphine Nalorphine Compound Qxymorphone Oxycodone * Hydromorphone	500 50,000 25,000 50,000 75,000 75,000 75,000 75,000 75,000 1,000 5,000 5,000 5,000 100 25,000
6-Acetylcodeine Codeine	2,000 250 ng/ml 10,000 1,750 1,000 20,000 20,000 50,000 50,000 50,000 50,000 500 300 500 300 500 300 100 15,000 5,000	Compound d,I-3,4-MDMA* d-Methamphetamine Compound d-Methamphetamine * I-Methamphetamine Procaine Trimethobenzamide Compound Methadone * Pheniramine Compound Hydrocodone Hydrocodone Morphine * Morphine 3-β-D-Glucuronide Nalorphine Compound	500 50,000 25,000 50,000 75,000 75,000 75,000 75,000 75,000 1,000 5,000 5,000 100 25,000
Compound d,I-3,4-MDA d,I-3,4-MDEA MET 500 ng/ml Compound Ephedrine p-Hydroxymethamphetamine d,I-3,4-MDMA d,I-3,4-MDMA d,I-3,4-MDEA MTD 300 ng/ml Compound Doxylamine 2-Ethylidene-1,5-Dimethyl- 1-3,3-Diphenylpyrolidine MOP 300 ng/ml Compound 6-Acetylcodeine Ethyl morphine Heroin OXY 100 ng/ml Compound 6-Acetylcodeine Codeine Dihydrocodeine Ethyl morphine Heroin OXY 100 ng/ml Compound 6-Acetylcodeine Codeine Dihydrocodeine	2,000 250 ng/ml 10,000 1,750 1,000 20,000 20,000 50,000 50,000 50,000 500 300 500 300 500 300 100 15,000 5,000 2,000	Compound d,I-3,4-MDMA* d-Methamphetamine Compound d-Methamphetamine * I-Methamphetamine * I-Methamphetamine Procaine Trimethobenzamide Compound Methadone * Pheniramine Compound Hydrocodone Hydrocodone Hydromorphone Morphine * Morphine Nalorphine Compound Qxymorphone Oxycodone * Hydromorphone	500 50,000 25,000 50,000 75,000 75,000 75,000 75,000 75,000 1,000 5,000 5,000 100 25,000
Compound d,I-3,4-MDA d,I-3,4-MDEA MET 500 ng/ml Compound Ephedrine p-Hydroxymethamphetamine d,I-3,4-MDMA d,I-3,4-MDMA d,I-3,4-MDEA MTD 300 ng/ml Compound Doxylamine 2-Ethylidene-1,5-Dimethyl- 1-3,3-Diphenylpyrolidine MOP 300 ng/ml Compound 6-Acetylcodeine Ethyl morphine Heroin OXY 100 ng/ml Compound 6-Acetylcodeine Codeine Dihydrocodeine Ethyl morphine Heroin OXY 100 ng/ml Compound 6-Acetylcodeine Codeine Dihydrocodeine Ethyl morphine Heroin	2,000 250 ng/ml 10,000 1,750 1,000 20,000 20,000 50,000 50,000 50,000 500 300 500 300 500 300 100 15,000 5,000 2,000	Compound d,I-3,4-MDMA* d-Methamphetamine Compound d-Methamphetamine * I-Methamphetamine * I-Methamphetamine Procaine Trimethobenzamide Compound Methadone * Pheniramine Compound Hydrocodone Hydrocodone Hydromorphone Morphine * Morphine Nalorphine Compound Qxymorphone Oxycodone * Hydromorphone	500 50,000 25,000 50,000 75,000 75,000 75,000 ng/ml 1,000 400 300

Metaphit	500	500 Phencyclidine Morpholine	
PPX 300ng/ml			
Compound	ng/ml	Compound	ng/ml
Propoxyphene *	300	Norpropoxyphene	500
TCA 1000 ng/ml			
Compound	ng/ml	Compound	ng/ml
Amitriptyline	1,000	Nordoxepin	1,000
Clomipramine	7,500	Nortriptyline *	1,000
Cyclobenzaprine	1,500	Perphenazine	50,000
Desipramine	750	Promazine	10,000
Doxepin	1,000	Protriptyline	350
Imipramine	750	Trimipramine	1,500
THC 50 ng/ml			
Compound	ng/ml	Compound	ng/ml
Cannabidiol	100,000	11-Hydroxy-∆9-THC	2,500
Cannabinol	50,000	Δ-8-Tetrahydrocannabinol	7,000
11-nor-∆8-THC-9-COOH	50	Δ-9-Tetrahydrocannabinol	10,500
11-nor-Δ9-THC-9-COOH *	50		

CONSUMER STUDY

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

INTERFERENCE

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

Acetaminophen	Alprazolam (except BZO assay)
Acetone	Amitriptyline (except TCA assay)
Acetylsalicylic acid (Aspirin)	Amobarbital (except BAR assay)
6-Acetylcodeine (except MOP & OXY	Amoxapine
assay)	d-Amphetamine (except AMP assay)
6-Acetylmorphine (except MOP assay)	I-Amphetamine (except AMP assay)
Amoxicillin	Ampicillin
Albumin	Apomorphine
Allobarbital (except BAR assay)	Aprobarbital (except BAR assay)
Alphenal (except BAR assay)	I-Ascorbic Acid (Vitamin C)
Aspartame	α-Hydroxy Alprazolam <i>(except BZO</i>
Atropine	assay)
Barbital (except BAR assay)	4-Hydroxy Phencyclidine (except PCP
Benzilic acid	assay)
Benzocaine (Ethyl p-Aminobenzoate)	p-Hydroxymethamphetamine (except
Benzoic acid	MET assay)
Benzoylecgonine (except COC assay)	11-Hydroxy-Δ-9-THC <i>(except THC assay)</i>
Benzphetamine	Ibuprofen
Bilirubin	Imipramine (except TCA assay)
Bromazepam <i>(except BZO assay)</i>	d,l-Isoproterenol
d-Brompheniramine	Ketamine
Buprenorphine (except BUPG assay)	Lidocaine
Butabarbital (except BAR assay)	Lorazepam (except BZO assay)
Butalbital (except BAR assay)	Lormetazepam (except BZO assay)
Butethal (except BAR assay)	Medazepam (except BZO assay)
Caffeine	Meperidine
Cannabidiol (except THC assay)	Metaphit (except PCP assay)
Cannabinol (except THC assay)	Methadone (except MTD assay)
Chlordiazepoxide (except BZO assay)	d-Methamphetamine (except MET &
Chloroquine	MDMA assay)
d,l-Chlorpheniramine	I-Methamphetamine (except MET
Chlorpromazine	assay)
Cholesterol	Methagualone
Clobazam (except BZO assay)	Methoxyphenamine
Clomipramine (except TCA assay)	(1R,2S) N-Methyl-Ephedrine
Clonazepam (except BZO assay)	2-Methylamine-Propiophenone
Cocaine	d,I-3,4-Methylenedioxyamphetamine
Codeine (except MOP & OXY assays)	(except AMP & MDMA assays)
Cortisone	d,l-3,4-methylenedioxyethylamphet
l-Cotinine	(except MET & MDMA assays)

Creatine Creatinine Cyclobenzaprine (except TCA assay) Delorazepam (except BZO assay) Deoxycorticosterone Desipramine (except TCA assay) Dextromethorphan Diazepam (except BZO assay) Dihydrocodeine (except MOP & OXY assay) 4-Dimethylaminoantipyrine Diphenhydramine Dopamine (3-Hydroxytyramine) Doxepin (except TCA assay) Doxylamine (except MTD assay) Ecgonine (except COC assay) Ecgonine Methyl Ester I-Epinephrine d,I-Ephedrine (except MET assay) Erythromycin Estazolam (except BZO assay) β-Estradiol Estrone-3-Sulfate Ethanol Ethyl Morphine (except MOP & OXY assay) Ethyl-p-aminobenzoate 2-Ethylidene-1,5-Dimethyl-1-3,3-Diphenylpyrolidone (except MTD assay) Flunitrazepam (except BZO assay) Flurazepam (except BZO assay) Furosemide Glucose Gentisic acid Glutethimide **Guaiacol Glyceryl Ether** Hemoglobin Heroin (except MOP assay) Hippuric acid Hydrochlorothizide Hydrocodone (except MOP & OXY assavs) Hydrocortisone Hydromorphone (except MOP & OXY assays) Protriptyline (except TCA assay) d-Pseudoephedrine Pyrrolidine Quinidine Quinine Ranitidine Riboflavin Salicylic acid Secobarbital (except BAR assay) Serotonin Sertraline Sodium Chloride Sulfamethazine Sulindac Temazepam (except BZO assay) Tetracycline Δ8-THC (except THC assay) Δ9-THC (except THC assay)

d,l-3,4-Methylenedioxymethamphetamine (except MET& MDMA assays) Methylphenidate Morphine (except MOP assay) Morphine-3-ß-D-Glucuronide (except MOP assay) Nalidixic acid Nalorphine (except for MOP assay) Naloxone d-Naproxen Niacinamide Nitrazepam (except BZO assay) Nordiazepam (except BZO assay) Nordoxepin (except TCA assay) Nicotine, (S)-Norepinephrine Norethindrone Norpropoxyphene (except PPX assay) Nortriptyline (except TCA assay) **Oxalic Acid** Oxazepam (except BZO assay) Oxolinic acid Oxycodone (except OXY assay) Oxymorphone (except OXY assay) Papaverine Penicillin-G (Benzylpenicillin) Pentazocine Pentobarbital (except BAR assay) Perphenazine (except TCA assay) Phenazepam (except BZO assay) Phencyclidine (except PCP assay) Phencyclidine Morpholine (except PCP assay) Pheniramine (except MTD assay) Phenobarbital (except BAR assay) Phenothiazine (Thiodiphenylamine) Phentermine (except AMP assay) Phenylephrine β-Phenylethylamine (except AMP assay) Prednisolone Prazepam (except BZO assay) Procaine (except MET assay) Promazine (except TCA assay) Promethazine Propoxyphene (except PPX assay) 11-nor-∆8-THC-9-Carboxylic Acid (except THC assay) 11-nor-Δ-9-THC-9-Carboxylic Acid (except THC assay) Thiamine Thioridazine Triazolam (except BZO assay) Trifluoperazine Trimethobenzamide (except MET assay) Trimipramine (except TCA assay) Tryptamine d,I-Tryptophan Tyramine d,I-Tyrosine

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GLOSSARY OF SYMBOLS

Symbol	Description	ISO 15223-1* Reference #	ISO 7000* Reference #
\triangle	Caution	5.4.4	0434A
\otimes	Do not reuse	5.4.2	1051
IVD	In vitro diagnostic medical device	5.5.1	Not applicable
i	Consult instructions for use	5.4.3	1641

*ISO 15223-1: Medical devices – Symbols to be used with medical device labels, labeling and information to be supplied – Part 1: General requirements ISO 7000: Graphical symbols for use on equipment – Registered symbols

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