

One-Step Drug of Abuse Dip Card Test

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One-Step Drug of Abuse Dip Card Test is an immunochromatographic assay for the qualitative detection of D-Amphetamine 1000, D-Amphetamine 500, Benzoylcegonine 300, Benzoylcegonine 150, 11-nor-Δ⁸-THC-9-COOH, Oxazepam, Methamphetamine 1000, Methamphetamine 500, Morphine 2000, Methadone, Phencyclidine, Oxycodone, Butalbital, Buprenorphine, Morphine 300, 2-Ethylidene-1,5-Dimethyl-3,3-Diphenylpyrrolidine, Propoxyphene, Methylenedioxymethamphetamine, and Nortriptyline in human urine at a cutoff concentration indicated in the table below.

The test may yield preliminary positive results when prescription drugs are ingested at prescribed doses. It is not intended to distinguish between prescription used and abuse of any drug. There are no uniformly recognized cutoff concentration levels for any drug in urine. The test provides only preliminary test results. A more specific alternative chemical method must be used in order to obtain a confirmed analytical result, Gas Chromatography/Mass Spectrometry (GC/MS) is the preferred confirmatory method. Clinical consideration and professional judgment should be exercised with any drug of abuse test result, particularly when the preliminary result is positive.

For *in vitro* diagnostic use only.

WHAT IS ONE-STEP DRUG OF ABUSE DIP CARD TEST?

A **One-Step Drug of Abuse Dip Card Test** is a rapid test for qualitative detection of D-Amphetamine 1000, D-Amphetamine 500, Benzoylcegonine 300, Benzoylcegonine 150, 11-nor-Δ⁸-THC-9-COOH, Oxazepam, Methamphetamine 1000, Methamphetamine 500, Morphine 2000, Methadone, Phencyclidine, Propoxyphene, Oxycodone, Butalbital, Buprenorphine, Morphine 300, 2-Ethylidene-1,5-Dimethyl-3,3-Diphenylpyrrolidine, Methylenedioxymethamphetamine, and Nortriptyline in human urine. **One-Step Drug of Abuse Dip Card Test** yields a positive result when a drug and/or its metabolite in urine is at or exceeds its cutoff concentration.

WHAT IS THE CUT-OFF VALUE AND APPROXIMATE DETECTION TIME?

Drug (Identifier)	Cutoff Level	Minimum Detection Time	Maximum Detection Time
D-Amphetamine	1000ng/mL	4-6 hours	2-3 days
D-Amphetamine	500ng/mL	4-6 hours	2-3 days
Benzoylcegonine	300ng/mL	2-6 hours	2-3 days
Benzoylcegonine	150ng/mL	2-6 hours	2-3 days
11-nor-Δ ⁸ -THC-9-COOH	50ng/mL	1-3 hours	1-7 days
Oxazepam	300ng/mL	2-7 hours	1-4 days
Methamphetamine	1000ng/mL	4-6 hours	2-3 days
Methamphetamine	500ng/mL	4-6 hours	2-3 days
Morphine	2000ng/mL	2-6 hours	1-3 days
Methadone	300ng/mL	3-8 hours	1-3 days
Oxycodone	100ng/mL	1-3 hours	1-2 days
Phencyclidine	25ng/mL	4-6 hours	7-14 days
Propoxyphene	300ng/mL	6-12 hours	1-3 days
Butalbital	300ng/mL	2-4 hours	1-3 weeks
Buprenorphine	10ng/mL	2-6 hours	2-4 days
Morphine	300ng/mL	2-6 hours	1-3 days
2-Ethylidene-1,5-Dimethyl-3,3-Diphenylpyrrolidine	300ng/mL	3-8 hours	1-3 days
Methylenedioxymethamphetamine	500ng/mL	2-7 hours	2-4 days
Nortriptyline	1000ng/mL	8-12 hours	2-7 days

PRINCIPLE

The **One-Step Drug of Abuse Dip Card Test** is an immunoassay. During testing, a urine specimen migrates upward on the test strip. A drug-positive urine specimen **will** not generate a colored line in the specific test line region of the strip, while a drug-negative urine specimen **will** generate a line in the test line region. A colored line **will** always appear at the control line region, indicating that proper volume of specimen has been added.

WARNINGS AND PRECAUTIONS

- For *in vitro* diagnostic use.
- For external use only.
- For single use. Discard after first use.
- Do not use the test if the pouch is punctured or not well sealed.
- Do not use after the expiration date.
- Keep out of the reach of children.
- The used test dip card and urine specimen should be discarded according to federal, state and local regulations.

CONTENTS OF THE PACKAGE

- Included in package:
- User Instruction
 - Dip Card (inside foil pouch)

Not included in package:

- Watch, Timer or Clock
- Collection Cup

STORAGE AND STABILITY

Store as packaged in the sealed pouch at 39°F - 86°F (4°C - 30°C). The test is stable through the expiration date printed on the sealed pouch. The test dip card must remain in the sealed pouch until use. Keep away from direct sunlight, moisture and heat. DO NOT FREEZE. Do not use beyond the expiration date.

WHEN TO COLLECT URINE FOR THE TEST?

You can use urine from any time of day. The minimum detection time varies for different drugs. (Refer to the approximate detection timetable).

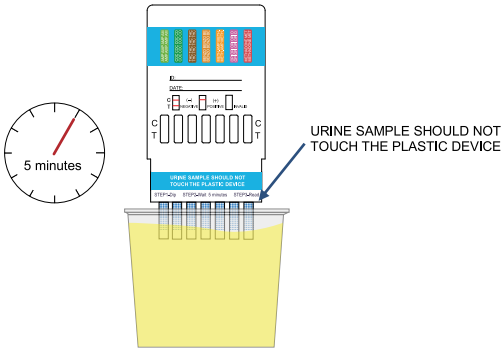
HOW TO COLLECT URINE?

- When you are ready to begin, remove the dip card from the sealed foil pouch.
- Notice the colored tape on each strip indicates the name of the drug you are testing for.
- Fill the collection cup with a fresh urine sample. Do not over-fill (see the max line mark).

HOW TO DO THE TEST?

- Remove the cap from the dip card. Insert the exposed test strips into the urine sample for 10 to 15 seconds. **DO NOT** let the urine sample touch the plastic to device, this could cause inconclusive drug test results.
- Insert the cap firmly back onto the dip card and lay it on a flat surface.
- Wait for 5 minutes (start timing immediately after dip card is taken out of the urine sample) and read the results. **DO NOT** read results after 5 minutes.

Note: Results after 5 minutes may be not accurate and should not be read.



READING THE RESULTS

Preliminary Positive (+)

If a line appears in the C - Control area, but NO line appears in the T - Test area, then it indicates a Preliminary Positive result for the corresponding drug.

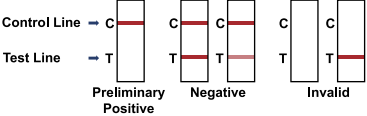
Negative (-)

If a line appears in both the C - Control and T - Test area, then it indicates a Negative result for the corresponding drug regardless of how dark or how light the line may appear.

Invalid

If at 5 minutes, NO line appears in the C - Control area, then the results are Invalid. In such case, retest with a new dip card.

Note: Each test strip needs to be looked at individually. Each line may vary in color and darkness or the rate at which the line appears. (DO NOT compare lines within the same test strip or between different test strips).



A positive test result does not always mean a person took illegal drugs and a negative test result does not always mean a person did not take illegal drugs. There are a number of factors that influence the reliability of drug tests. Certain drugs of abuse tests are more accurate than others.

IMPORTANT: The result you obtained is called preliminary for a reason. The sample must be tested by laboratory in order to determine if a drug of abuse is actually present.

WHAT IS A FALSE POSITIVE TEST?

The definition of a false positive test would be an instance where the test result from the **One-Step Drug of Abuse Dip Card Test** is positive, even though the initial target drug is not present in the sample. The most common causes of a false positive test are cross reactants. Certain foods and medicines, diet plan drugs and nutritional supplements may also cause a false positive test result with this product.

WHAT IS A FALSE NEGATIVE TEST?

The definition of a false negative test is that the initial target drug is present, but isn't detected by the **One-Step Drug of Abuse Dip Card Test**. If the sample is diluted or if the sample is tainted or contaminated with a substance, this could cause false negative results.

TEST LIMITATIONS

- One-Step Drug of Abuse Dip Card 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.
- There is a possibility that interfering substances in the urine specimen may cause erroneous results.
- Substances, such as bleach and/or alum, in urine specimens may produce erroneous results.
- A positive result does not indicate intoxication, the concentration of drug in the urine, or the route of drug administration.
- A negative result may not necessarily indicate drug-free urine. A negative result can be obtained when drug is present but below the cutoff level of the test.
- The test does not distinguish between drugs of abuse and certain medications.
- A positive test result may be obtained from certain foods or food supplements.

QUALITY CONTROL

If you work in a laboratory, you should perform quality control testing and read this section. 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.

Control standards are not supplied with this kit. However, it is recommended that positive and negative controls be tested as good laboratory practice to confirm the test procedure and to verify proper test performance. Quality control testing should be done with each new lot and each new shipment. It should be done every thirty days to check storage. Please contact our Technical Support at 1-826-443-8480 for controls that work with the dip card.

PERFORMANCE CHARACTERISTICS

Eighty clinical urine specimens were analyzed by GC/MS and by the **One-Step Drug of Abuse Dip Card Test**. Each test was read by three viewers. Samples were divided by concentration into five categories: drug-free, less than half the cutoff, near cutoff negative, near cutoff positive, and high positive. Results were as follows:

Accuracy - D-Amphetamine 1000

Viewer A:

WHPM Result	Drug-free	Less than half the cutoff Concentration by GC/MS analysis	Near cutoff negative (Between 50% below the cutoff and the cutoff concentration)	Near cutoff positive (Between the cutoff and 50% above the cutoff concentration)	High positive (Greater than 50% above the cutoff concentration)
Positive	0	0	1	10	26
Negative	10	10	19	4	0

% agreement among positives is 90%

% agreement among negatives is 97.5%

Viewer B:

WHPM Result	Drug-free	Less than half the cutoff Concentration by GC/MS analysis	Near cutoff negative (Between 50% below the cutoff and the cutoff concentration)	Near cutoff positive (Between the cutoff and 50% above the cutoff concentration)	High positive (Greater than 50% above the cutoff concentration)
Positive	0	0	1	11	26
Negative	10	10	19	3	0

% agreement among positives is 92.5%

% agreement among negatives is 97.5%

Viewer C:

WHPM Result	Drug-free	Less than half the cutoff Concentration by GC/MS analysis	Near cutoff negative (Between 50% below the cutoff and the cutoff concentration)	Near cutoff positive (Between the cutoff and 50% above the cutoff concentration)	High positive (Greater than 50% above the cutoff concentration)
Positive	0	0	1	12	26
Negative	10	10	19	2	0

% agreement among positives is 95%

% agreement among negatives is 97.5%

From the results of the above tables, the total results are shown below for D-Amphetamine 1000: The average positive agreement is 92.5%. The average negative agreement is 97.5%.

Accuracy - D-Amphetamine 500

Viewer A:

WHPM Result	Drug-free	Less than half the cutoff Concentration by GC/MS analysis	Near cutoff negative (Between 50% below the cutoff and the cutoff concentration)	Near cutoff positive (Between the cutoff and 50% above the cutoff concentration)	High positive (Greater than 50% above the cutoff concentration)
Positive	0	0	1	13	26
Negative	10	10	19	1	0

% agreement among positives is 97.5%

% agreement among negatives is 97.5%

Viewer B:

WHPM Result	Drug-free	Less than half the cutoff Concentration by GC/MS analysis	Near cutoff negative (Between 50% below the cutoff and the cutoff concentration)	Near cutoff positive (Between the cutoff and 50% above the cutoff concentration)	High positive (Greater than 50% above the cutoff concentration)
Positive	0	0	0	13	26
Negative	10	10	20	1	0

% agreement among positives is 97.5%

% agreement among negatives is 100%

Viewer C:

WHPM Result	Drug-free	Less than half the cutoff Concentration by GC/MS analysis	Near cutoff negative (Between 50% below the cutoff and the cutoff concentration)	Near cutoff positive (Between the cutoff and 50% above the cutoff concentration)	High positive (Greater than 50% above the cutoff concentration)
Positive	0	0	1	13	26
Negative	10	10	19	1	0

% agreement among positives is 97.5%

% agreement among negatives is 97.5%

From the results of the above tables, the total results are shown below for D-Amphetamine 500: The average positive agreement is 97.5%. The average negative agreement is 98.3%.

Viewer A:

% agreement among positives is 90%

% agreement among negatives is 97.5%

11

% agreement among positives is 90%

% agreement among negatives is 97.5%

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% agreement among positives is 92.5%
% agreement among negatives is 100%

Accuracy - Benzoylecgonine 150

Viewer A:

% agreement among positives is 97.5%
% agreement among negatives is 100%

11

% agreement among positives is 97.5%
% agreement among negatives is 100%

Viewer 3:

% agreement among positives is 97.5%

% agreement among negatives is 97.5%

Accuracy - 11-nor- Δ^9 -THC-9-COOH

Viewer A:

% agreement among positives is 100%
% agreement among negatives is 95%

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% agreement among positives is 100%
% agreement among negatives is 97.5%

11

% agreement among positives is 100%
% agreement among negatives is 97.5%

Accuracy - Oxazepam

11/11/2016

% agreement among positives is 95%

% agreement among negatives is 100%

11

% agreement among positives is 97.5%
% agreement among negatives is 100%

11

% agreement among positives is 95%

% agreement among negatives is 100%

Accuracy - Methamphetamine 1000

11

% agreement among positives is 97.5%
% agreement among negatives is 100%

11

% agreement among positives is 97.5%

% agreement among negatives is 100%

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% agreement among positives is 95%
% agreement among negatives is 100%

Accuracy - Methamphetamine 500

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% agreement among positives is 97.5%
% agreement among negatives is 97.5%

11/11/2016

% agreement among positives is 97.5%

TABLE 1

% agreement among positives is 97.5%

Accuracy - Morphine 2000

[illegible]

% agreement among positives is 97.5%

% agreement among positives is 97.5%

% agreement among negatives is 100%

VIEWER'S

% agreement among positives is 97.5%

From the results of the above tables, the total results are shown below for Morphine 2000:
The average positive agreement is 97.5%.
The average negative agreement is 100%.

Accuracy - 2-Ethylidene-1,5-Dimethyl-3,3-Diphenylpyrrolidine

Viewer A:

WHPM Result	Drug-free	Less than half the cutoff Concentration by GC/MS analysis	Near cutoff negative (Between 50% below the cutoff and the cutoff concentration)	Near cutoff positive (Between the cutoff and 50% above the cutoff concentration)	High positive (Greater than 50% above the cutoff concentration)
Positive	0	0	1	13	26
Negative	10	10	19	1	0

% agreement among positives is 97.5%

% agreement among negatives is 97.5%

Viewer B:

WHPM Result	Drug-free	Less than half the cutoff Concentration by GC/MS analysis	Near cutoff negative (Between 50% below the cutoff and the cutoff concentration)	Near cutoff positive (Between the cutoff and 50% above the cutoff concentration)	High positive (Greater than 50% above the cutoff concentration)
Positive	0	0	1	14	26
Negative	10	10	19	0	0

% agreement among positives is 100%

% agreement among negatives is 97.5%

Viewer C:

WHPM Result	Drug-free	Less than half the cutoff Concentration by GC/MS analysis	Near cutoff negative (Between 50% below the cutoff and the cutoff concentration)	Near cutoff positive (Between the cutoff and 50% above the cutoff concentration)	High positive (Greater than 50% above the cutoff concentration)
Positive	0	0	1	13	26
Negative	10	10	19	1	0

% agreement among positives is 97.5%

% agreement among negatives is 97.5%

From the results of the above tables, the total results are shown below for 2-Ethylidene-1,5-Dimethyl-3,3-Diphenylpyrrolidine:

The average positive agreement is 98.3%.

The average negative agreement is 97.5%.

Accuracy - Methylenedioxymethamphetamine

Viewer A:

WHPM Result	Drug-free	Less than half the cutoff Concentration by GC/MS analysis	Near cutoff negative (Between 50% below the cutoff and the cutoff concentration)	Near cutoff positive (Between the cutoff and 50% above the cutoff concentration)	High positive (Greater than 50% above the cutoff concentration)
Positive	0	0	0	13	26
Negative	10	10	20	1	0

% agreement among positives is 97.5%

% agreement among negatives is 100%

Viewer B:

WHPM Result	Drug-free	Less than half the cutoff Concentration by GC/MS analysis	Near cutoff negative (Between 50% below the cutoff and the cutoff concentration)	Near cutoff positive (Between the cutoff and 50% above the cutoff concentration)	High positive (Greater than 50% above the cutoff concentration)
Positive	0	0	1	14	26
Negative	10	10	19	0	0

% agreement among positives is 100%

% agreement among negatives is 97.5%

Viewer C:

WHPM Result	Drug-free	Less than half the cutoff Concentration by GC/MS analysis	Near cutoff negative (Between 50% below the cutoff and the cutoff concentration)	Near cutoff positive (Between the cutoff and 50% above the cutoff concentration)	High positive (Greater than 50% above the cutoff concentration)
Positive	0	0	1	13	26
Negative	10	10	19	1	0

% agreement among positives is 97.5%

% agreement among negatives is 97.5%

From the results of the above tables, the total results are shown below for Methylenedioxymethamphetamine:

The average positive agreement is 98.3%.

The average negative agreement is 98.3%.

Accuracy - Nortriptyline

Viewer A:

WHPM Result	Drug-free	Less than half the cutoff Concentration by GC/MS analysis	Near cutoff negative (Between 50% below the cutoff and the cutoff concentration)	Near cutoff positive (Between the cutoff and 50% above the cutoff concentration)	High positive (Greater than 50% above the cutoff concentration)
Positive	0	0	1	14	26
Negative	10	10	19	0	0

% agreement among positives is 100%

% agreement among negatives is 97.5%

Viewer B:

WHPM Result	Drug-free	Less than half the cutoff Concentration by GC/MS analysis	Near cutoff negative (Between 50% below the cutoff and the cutoff concentration)	Near cutoff positive (Between the cutoff and 50% above the cutoff concentration)	High positive (Greater than 50% above the cutoff concentration)
Positive	0	0	1	13	26
Negative	10	10	19	1	0

% agreement among positives is 97.5%

% agreement among negatives is 97.5%

Viewer C:

WHPM Result	Drug-free	Less than half the cutoff Concentration by GC/MS analysis	Near cutoff negative (Between 50% below the cutoff and the cutoff concentration)	Near cutoff positive (Between the cutoff and 50% above the cutoff concentration)	High positive (Greater than 50% above the cutoff concentration)
Positive	0	0	1	13	26
Negative	10	10	19	1	0

% agreement among positives is 97.5%

% agreement among negatives is 97.5%

From the results of the above tables, the total results are shown below for Nortriptyline:

The average positive agreement is 98.3%.

The average negative agreement is 97.5%.

Precision and Sensitivity - D-Amphetamine 1000

Lot 1

Approximate Concentration of Sample (ng/mL)	Number of Determinations	Results Negative/Positive
0	50	50/0
250	50	50/0
500	50	50/0
750	50	50/0
1000	50	4/46
1250	50	0/50
1500	50	0/50
1750	50	0/50
2000	50	0/50

Lot 2

Approximate Concentration of Sample (ng/mL)	Number of Determinations	Results Negative/Positive
0	50	50/0
250	50	50/0
500	50	50/0
750	50	50/0
1000	50	3/47
1250	50	0/50
1500	50	0/50
1750	50	0/50
2000	50	0/50

Lot 3

Approximate Concentration of Sample (ng/mL)	Number of Determinations	Results Negative/Positive
0	50	50/0
250	50	50/0
500	50	50/0
750	50	50/0
1000	50	3/47
1250	50	0/50
1500	50	0/50
1750	50	0/50
2000	50	0/50

Precision and Sensitivity - D-Amphetamine 500

Lot 1

Approximate Concentration of Sample (ng/mL)	Number of Determinations	Results Negative/Positive
0	50	50/0
125	50	50/0
250	50	50/0
375	50	50/0
500	50	3/47
625	50	0/50
750	50	0/50
875	50	0/50
1000	50	0/50

Lot 2

Approximate Concentration of Sample (ng/mL)	Number of Determinations	Results Negative/Positive
0	50	50/0
125	50	50/0
250	50	50/0
375	50	50/0
500	50	2/48
625	50	0/50
750	50	0/50
875	50	0/50
1000	50	0/50

Lot 3

Approximate Concentration of Sample (ng/mL)	Number of Determinations	Results Negative/Positive
0	50	50/0
125	50	50/0
250	50	50/0
375	50	50/0
500	50	2/48
625	50	0/50
750	50	0/50
875	50	0/50
1000	50	0/50

Precision and Sensitivity - Benzoylcgonine 300

Lot 1

Approximate Concentration of Sample (ng/mL)	Number of Determinations	Results Negative/Positive
0	50	50/0
75	50	50/0
150	50	50/0
225	50	50/0
300	50	3/47
375	50	0/50
450	50	0/50
525	50	0/50
600	50	0/50

Lot 2

Approximate Concentration of Sample (ng/mL)	Number of Determinations	Results Negative/Positive
0	50	50/0
75	50	50/0
150	50	50/0
225	50	50/0
300	50	4/46
375	50	0/50
450	50	0/50
525	50	0/50
600	50	0/50

Lot 3

Approximate Concentration of Sample (ng/mL)	Number of Determinations	Results Negative/Positive
0	50	50/0
75	50	50/0
150	50	50/0
225	50	50/0
300	50	3/47
375	50	0/50
450	50	0/50
525	50	0/50
600	50	0/50

Precision and Sensitivity - Benzoylcgonine 150

Lot 1

Approximate Concentration of Sample (ng/mL)	Number of Determinations	Results Negative/Positive
0	50	50/0
37.5	50	50/0
75	50	50/0
112.5	50	50/0
150	50	2/48
187.5	50	0/50
225	50	0/50
262.5	50	0/50
300	50	0/50

Lot 2		
Approximate Concentration of Sample (ng/mL)	Number of Determinations	Results Negative/Positive
0	50	50/0
37.5	50	50/0
75	50	50/0
112.5	50	50/0
150	50	3/47
187.5	50	0/50
225	50	0/50
262.5	50	0/50
300	50	0/50

Lot 3		
Approximate Concentration of Sample (ng/mL)	Number of Determinations	Results Negative/Positive
0	50	50/0
37.5	50	50/0
75	50	50/0
112.5	50	50/0
150	50	3/47
187.5	50	0/50
225	50	0/50
262.5	50	0/50
300	50	0/50

Precision and Sensitivity - 11-nor- Δ^8 -THC-9-COOH

Lot 1		
Approximate Concentration of Sample (ng/mL)	Number of Determinations	Results Negative/Positive
0	50	50/0
12.5	50	50/0
25	50	50/0
37.5	50	50/0
50	50	4/46
62.5	50	0/50
75	50	0/50
87.5	50	0/50
100	50	0/50

Lot 2		
Approximate Concentration of Sample (ng/mL)	Number of Determinations	Results Negative/Positive
0	50	50/0
12.5	50	50/0
25	50	50/0
37.5	50	50/0
50	50	3/47
62.5	50	0/50
75	50	0/50
87.5	50	0/50
100	50	0/50

Lot 3		
Approximate Concentration of Sample (ng/mL)	Number of Determinations	Results Negative/Positive
0	50	50/0
12.5	50	50/0
25	50	50/0
37.5	50	50/0
50	50	3/47
62.5	50	0/50
75	50	0/50
87.5	50	0/50
100	50	0/50

Precision and Sensitivity - Oxazepam

Lot 1		
Approximate Concentration of Sample (ng/mL)	Number of Determinations	Results Negative/Positive
0	50	50/0
75	50	50/0
150	50	50/0
225	50	50/0
300	50	3/47
375	50	0/50
450	50	0/50
525	50	0/50
600	50	0/50

Lot 2		
Approximate Concentration of Sample (ng/mL)	Number of Determinations	Results Negative/Positive
0	50	50/0
75	50	50/0
150	50	50/0
225	50	50/0
300	50	4/46
375	50	0/50
450	50	0/50
525	50	0/50
600	50	0/50

Lot 3		
Approximate Concentration of Sample (ng/mL)	Number of Determinations	Results Negative/Positive
0	50	50/0
75	50	50/0
150	50	50/0
225	50	50/0
300	50	3/47
375	50	0/50
450	50	0/50
525	50	0/50
600	50	0/50

Precision and Sensitivity - Methamphetamine 1000

Lot 1		
Approximate Concentration of Sample (ng/mL)	Number of Determinations	Results Negative/Positive
0	50	50/0
250	50	50/0
500	50	50/0
750	50	50/0
1000	50	4/46
1250	50	0/50
1500	50	0/50
1750	50	0/50
2000	50	0/50

Lot 2		
Approximate Concentration of Sample (ng/mL)	Number of Determinations	Results Negative/Positive
0	50	50/0
250	50	50/0
500	50	50/0
750	50	50/0
1000	50	3/47
1250	50	0/50
1500	50	0/50
1750	50	0/50
2000	50	0/50

Lot 3		
Approximate Concentration of Sample (ng/mL)	Number of Determinations	Results Negative/Positive
0	50	50/0
250	50	50/0
500	50	50/0
750	50	50/0
1000	50	3/47
1250	50	0/50
1500	50	0/50
1750	50	0/50
2000	50	0/50

Precision and Sensitivity - Methamphetamine 500

Lot 1		
Approximate Concentration of Sample (ng/mL)	Number of Determinations	Results Negative/Positive
0	50	50/0
125	50	50/0
250	50	50/0
375	50	50/0
500	50	3/47
625	50	0/50
750	50	0/50
875	50	0/50
1000	50	0/50

Lot 2		
Approximate Concentration of Sample (ng/mL)	Number of Determinations	Results Negative/Positive
0	50	50/0
125	50	50/0
250	50	50/0
375	50	50/0
500	50	4/46
625	50	0/50
750	50	0/50
875	50	0/50
1000	50	0/50

Lot 3		
Approximate Concentration of Sample (ng/mL)	Number of Determinations	Results Negative/Positive
0	50	50/0
125	50	50/0
250	50	50/0
375	50	50/0
500	50	3/47
625	50	0/50
750	50	0/50
875	50	0/50
1000	50	0/50

Precision and Sensitivity - Morphine 2000

Lot 1		
Approximate Concentration of Sample (ng/mL)	Number of Determinations	Results Negative/Positive
0	50	50/0
500	50	50/0
1000	50	50/0
1500	50	50/0
2000	50	3/47
2500	50	0/50
3000	50	0/50
3500	50	0/50
4000	50	0/50

Lot 2		
Approximate Concentration of Sample (ng/mL)	Number of Determinations	Results Negative/Positive
0	50	50/0
500	50	50/0
1000	50	50/0
1500	50	50/0
2000	50	3/47
2500	50	0/50
3000	50	0/50
3500	50	0/50
4000	50	0/50

Lot 3		
Approximate Concentration of Sample (ng/mL)	Number of Determinations	Results Negative/Positive
0	50	50/0
500	50	50/0
1000	50	50/0
1500	50	50/0
2000	50	4/46
2500	50	0/50
3000	50	0/50
3500	50	0/50
4000	50	0/50

Precision and Sensitivity - Methadone

Lot 1		
Approximate Concentration of Sample (ng/mL)	Number of Determinations	Results Negative/Positive
0	50	50/0
75	50	50/0
150	50	50/0
225	50	50/0
300	50	3/47
375	50	0/50
450	50	0/50
525	50	0/50
600	50	0/50

Lot 2		
Approximate Concentration of Sample (ng/mL)	Number of Determinations	Results Negative/Positive
0	50	50/0
75	50	50/0
150	50	50/0
225	50	50/0
300	50	3/47
375	50	0/50
450	50	0/50
525	50	0/50
600	50	0/50

Lot 3		
Approximate Concentration of Sample (ng/mL)	Number of Determinations	Results Negative/Positive
0	50	50/0
75	50	50/0
150	50	50/0
225	50	50/0
300	50	1/49
375	50	0/50
450	50	0/50
525	50	0/50
600	50	0/50

Precision and Sensitivity - Oxycodone

Lot 1		
Approximate Concentration of Sample (ng/mL)	Number of Determinations	Results Negative/Positive
0	50	50/0
25	50	50/0
50	50	50/0
75	50	50/0
100	50	4/46
125	50	0/50
150	50	0/50
175	50	0/50
200	50	0/50

Lot 2		
Approximate Concentration of Sample (ng/mL)	Number of Determinations	Results Negative/Positive
0	50	50/0
25	50	50/0
50	50	50/0
75	50	50/0
100	50	3/47
125	50	0/50
150	50	0/50
175	50	0/50
200	50	0/50

Lot 3		
Approximate Concentration of Sample (ng/mL)	Number of Determinations	Results Negative/Positive
0	50	50/0
25	50	50/0
50	50	50/0
75	50	50/0
100	50	3/47
125	50	0/50
150	50	0/50
175	50	0/50
200	50	0/50

Precision and Sensitivity - Phencyclidine

Lot 1		
Approximate Concentration of Sample (ng/mL)	Number of Determinations	Results Negative/Positive
0	50	50/0
6.3	50	50/0
12.5	50	50/0
18.8	50	50/0
25	50	3/47
31.3	50	0/50
37.5	50	0/50
43.8	50	0/50
50	50	0/50

Lot 2		
Approximate Concentration of Sample (ng/mL)	Number of Determinations	Results Negative/Positive
0	50	50/0
6.3	50	50/0
12.5	50	50/0
18.8	50	50/0
25	50	2/48
31.3	50	0/50
37.5	50	0/50
43.8	50	0/50
50	50	0/50

Lot 3		
Approximate Concentration of Sample (ng/mL)	Number of Determinations	Results Negative/Positive
0	50	50/0
6.3	50	50/0
12.5	50	50/0
18.8	50	50/0
25	50	2/48
31.3	50	0/50
37.5	50	0/50
43.8	50	0/50
50	50	0/50

Precision and Sensitivity - Propoxyphene

Lot 1		
Approximate Concentration of Sample (ng/mL)	Number of Determinations	Results Negative/Positive
0	50	50/0
75	50	50/0
150	50	50/0
225	50	50/0
300	50	4/46
375	50	0/50
450	50	0/50
525	50	0/50
600	50	0/50

Lot 2		
Approximate Concentration of Sample (ng/mL)	Number of Determinations	Results Negative/Positive
0	50	50/0
75	50	50/0
150	50	50/0
225	50	50/0
300	50	3/47
375	50	0/50
450	50	0/50
525	50	0/50
600	50	0/50

Lot 3		
Approximate Concentration of Sample (ng/mL)	Number of Determinations	Results Negative/Positive
0	50	50/0
75	50	50/0
150	50	50/0
225	50	50/0
300	50	4/46
375	50	0/50
450	50	0/50
525	50	0/50
600	50	0/50

Precision and Sensitivity - Butalbital

Lot 1		
Approximate Concentration of Sample (ng/mL)	Number of Determinations	Results Negative/Positive
0	50	50/0
75	50	50/0
150	50	50/0
225	50	50/0
300	50	3/47
375	50	0/50
450	50	0/50
525	50	0/50
600	50	0/50

Lot 2		
Approximate Concentration of Sample (ng/mL)	Number of Determinations	Results Negative/Positive
0	50	50/0
75	50	50/0
150	50	50/0
225	50	50/0
300	50	4/46
375	50	0/50
450	50	0/50
525	50	0/50
600	50	0/50

Lot 3		
Approximate Concentration of Sample (ng/mL)	Number of Determinations	Results Negative/Positive
0	50	50/0
75	50	50/0
150	50	50/0
225	50	50/0
300	50	3/47
375	50	0/50
450	50	0/50
525	50	0/50
600	50	0/50

Precision and Sensitivity - Buprenorphine

Lot 1		
Approximate Concentration of Sample (ng/mL)	Number of Determinations	Results Negative/Positive
0	50	50/0
2.5	50	50/0
5	50	50/0
7.5	50	50/0
10	50	3/47
12.5	50	0/50
15	50	0/50
17.5	50	0/50
20	50	0/50

Lot 2		
Approximate Concentration of Sample (ng/mL)	Number of Determinations	Results Negative/Positive
0	50	50/0
2.5	50	50/0
5	50	50/0
7.5	50	50/0
10	50	3/47
12.5	50	0/50
15	50	0/50
17.5	50	0/50
20	50	0/50

Lot 3		
Approximate Concentration of Sample (ng/mL)	Number of Determinations	Results Negative/Positive
0	50	50/0
2.5	50	50/0
5	50	50/0
7.5	50	50/0
10	50	3/47
12.5	50	0/50
15	50	0/50
17.5	50	0/50
20	50	0/50

Precision and Sensitivity - Morphine 300

Lot 1		
Approximate concentration of sample (ng/mL)	Number of determinations	Results Negative/Positive
0	50	50/0
75	50	50/0
150	50	50/0
225	50	50/0
300	50	2/48
375	50	0/50
450	50	0/50
525	50	0/50
600	50	0/50

Lot 2		
Approximate concentration of sample (ng/mL)	Number of determinations	Results Negative/Positive
0	50	50/0
75	50	50/0
150	50	50/0
225	50	50/0
300	50	1/49
375	50	0/50
450	50	0/50
525	50	0/50
600	50	0/50

Lot 3		
Approximate concentration of sample (ng/mL)	Number of determinations	Results Negative/Positive
0	50	50/0
75	50	50/0
150	50	50/0
225	50	50/0
300	50	2/48
375	50	0/50
450	50	0/50
525	50	0/50
600	50	0/50

Precision and Sensitivity - 2-Ethylidene-1,5-Dimethyl-3,3-Diphenylpyrrolidine

Lot 1		
Approximate Concentration of Sample (ng/mL)	Number of Determinations	Results Negative/Positive
0	50	50/0
75	50	50/0
150	50	50/0
225	50	50/0
300	50	3/47
375	50	0/50
450	50	0/50
525	50	0/50
600	50	0/50

Lot 2		
Approximate Concentration of Sample (ng/mL)	Number of Determinations	Results Negative/Positive
0	50	50/0
75	50	50/0
150	50	50/0
225	50	50/0
300	50	2/48
375	50	0/50
450	50	0/50
525	50	0/50
600	50	0/50

Lot 3		
Approximate Concentration of Sample (ng/mL)	Number of Determinations	Results Negative/Positive
0	50	50/0
75	50	50/0
150	50	50/0
225	50	50/0
300	50	2/48
375	50	0/50
450	50	0/50
525	50	0/50
600	50	0/50

Precision and Sensitivity - Methylenedioxymethamphetamine

Lot 1		
Approximate Concentration of Sample (ng/mL)	Number of Determinations	Results Negative/Positive
0	50	50/0
125	50	50/0
250	50	50/0
375	50	50/0
500	50	2/48
625	50	0/50
750	50	0/50
875	50	0/50
1000	50	0/50

Lot 2		
Approximate Concentration of Sample (ng/mL)	Number of Determinations	Results Negative/Positive
0	50	50/0
125	50	50/0
250	50	50/0
375	50	50/0
500	50	3/47
625	50	0/50
750	50	0/50
875	50	0/50
1000	50	0/50

Lot 3		
Approximate Concentration of Sample (ng/mL)	Number of Determinations	Results Negative/Positive
0	50	50/0
125	50	50/0
250	50	50/0
375	50	50/0
500	50	3/47
625	50	0/50
750	50	0/50
875	50	0/50
1000	50	0/50

Precision and Sensitivity - Nortriptyline

Lot 1		
Approximate Concentration of Sample (ng/mL)	Number of Determinations	Results Negative/Positive
0	50	50/0
250	50	50/0
500	50	50/0
750	50	50/0
1000	50	3/47
1250	50	0/50
1500	50	0/50
1750	50	0/50
2000	50	0/50

Lot 2		
Approximate Concentration of Sample (ng/mL)	Number of Determinations	Results Negative/Positive
0	50	50/0
250	50	50/0
500	50	50/0
750	50	50/0
1000	50	2/48
1250	50	0/50
1500	50	0/50
1750	50	0/50
2000	50	0/50

Lot 3		
Approximate Concentration of Sample (ng/mL)	Number of Determinations	Results Negative/Positive
0	50	50/0
250	50	50/0
500	50	50/0
750	50	50/0
1000	50	2/48
1250	50	0/50
1500	50	0/50
1750	50	0/50
2000	50	0/50

Specificity and Cross Reactivity

To test the specificity of the test, the test device was used to test D-Amphetamine 1000, D-Amphetamine 500, Benzoylcegonine 300, Benzoylcegonine 150, 11-nor- Δ^8 -THC-9-COOH, Oxazepam, Methamphetamine 1000, Methamphetamine 500, Morphine 2000, Methadone, Phencyclidine, Propoxyphene, Oxycodone, Butalbital, Buprenorphine, Morphine 300, 2-Ethylidene -1, 5-Dimethyl-3, 3-Diphenylpyrrolidine, Methylenedioxymethamphetamine, and Nortriptyline drug metabolites and other components of the same class that are likely to be present in urine. All the components were added to drug-free normal human urine. The following structurally related compounds produced positive results with the test when tested at levels equal to or greater than the concentrations listed below.

D-Amphetamine 1000	Result
(D-Amphetamine, Cutoff = 1,000ng/mL)	Positive at 1000ng/mL
L-Amphetamine	Positive at 100000ng/mL
DL-Amphetamine	Positive at 500ng/mL

(\pm)-3,4-Methylenedioxyamphetamine (MDA)	Positive at 1300ng/mL
Phentermine	Positive at 100000ng/mL
Apomorphine	Positive at 50000ng/mL
β -Phenethylamine	Positive at 25000ng/mL
Tyramine	Positive at 10000ng/mL
Tryptamine	Positive at 25000ng/mL
D-Methamphetamine	>100000
L-Methamphetamine	>100000
Ephedrine	>100000
3,4-Methylenedioxyethylamphetamine (MDE)	>100000

D-Amphetamine 500	Result
(D-Amphetamine, Cutoff = 500ng/mL)	Positive at 500ng/mL
L-Amphetamine	Positive at 60000ng/mL
DL-Amphetamine	Positive at 1000ng/mL
Methylenedioxyamphetamine (MDA)	Positive at 600ng/mL
R-($-$)-Apomorphine	Positive at 13000ng/mL
β -Phenylethylamine	Positive at 8000ng/mL
Tyramine	Positive at 5000ng/mL
Tryptamine	Positive at 100000ng/mL
Hydroxyamphetamine	Positive at 600ng/mL
D-Pseudoephedrine	Negative at $\geq 10^5$ ng/mL
D-Methamphetamine	Negative at $\geq 10^5$ ng/mL
L-Methamphetamine	Negative at $\geq 10^5$ ng/mL
(\pm)-Methamphetamine	Negative at $\geq 10^5$ ng/mL
Ephedrine	Negative at $\geq 10^5$ ng/mL
3,4-Methylenedioxy-N-ethylamphetamine (MDEA)	Negative at $\geq 10^5$ ng/mL
3,4-Methylenedioxymethamphetamine (MDMA)	Negative at $\geq 10^5$ ng/mL
Phentermine	Negative at $\geq 10^5$ ng/mL

Benzoylcegonine 300	Result
(Benzoylcegonine, Cutoff = 300ng/mL)	Positive at 300ng/mL
Cocaine HCl	Positive at 500ng/mL
Cocaethylene	>100000
Ecgonine	>100000

Benzoylcegonine 150	Result
(Benzoylcegonine, Cutoff = 150ng/mL)	Positive at 150ng/mL
Cocaine HCl	Positive at 3000ng/mL
Norcocaine	Negative at $\geq 10^5$ ng/mL
Cocaethylene	Negative at $\geq 10^5$ ng/mL
Ecgonine	Negative at $\geq 10^5$ ng/mL

11-nor- Δ^8 -THC-9-COOH	Result
(11-nor- Δ^8 -THC-9-COOH, Cutoff = 50ng/mL)	Positive at 50ng/mL
11-hydroxy- Δ^8 -Tetrahydrocannabinol	Positive at 15000ng/mL
Δ^8 -Tetrahydrocannabinol	Positive at 8000ng/mL
Δ^9 -Tetrahydrocannabinol	Positive at 7000ng/mL
Cannabinol	>200000
Cannabidiol	>200000

Oxazepam	Result
(Oxazepam, Cutoff = 300ng/mL)	Positive at 300ng/mL
Alprazolam	Positive at 125ng/mL
α -Hydroxyalprazolam	Positive at 2500ng/mL
Bromazepam	Positive at 1565ng/mL
Chlordiazepoxide	Positive at 1560ng/mL
Clobazam	Positive at 65ng/mL
Clonazepam	Positive at 10000ng/mL
Clorazepate Dipotassium	Positive at 195ng/mL
Delorazepam	Positive at 1560ng/mL
Desalkylflurazepam	Positive at 1565ng/mL
Diazepam	Positive at 115ng/mL
Estazolam	Positive at 165ng/mL
Flunitrazepam	Positive at 168ng/mL
Midazolam	Positive at 6500ng/mL
Nitrazepam	Positive at 300ng/mL
Norchlordiazepoxide	Positive at 250ng/mL
Nordiazepam	Positive at 400ng/mL
Temazepam	Positive at 100ng/mL
Triazolam	Positive at 2500ng/mL
DL-Lorazepam	Negative at $\leq 10^5$ ng/mL
Methamphetamine	Negative at $\leq 10^5$ ng/mL
Morphine	Negative at $\leq 10^5$ ng/mL

Methamphetamine 1000	Result
(D-Methamphetamine, Cutoff = 1000ng/mL)	Positive at 1000ng/mL
(±)-3,4-Methylenedioxy-n-ethylamphetamine (MDEA)	Positive at 41600ng/mL
DL-Methamphetamine	Positive at 1000ng/mL
p-Hydroxymethamphetamine	Positive at 27000ng/mL
(±)-3,4-Methylenedioxy-methamphetamine (MDMA)	Positive at 8000ng/mL
L-Methamphetamine	Positive at 10000ng/mL
Trimethobenzamide	Negative at ≤ 10 ⁵ ng/mL
Chloroquine	Negative at ≤ 10 ⁵ ng/mL
Ephedrine	Negative at ≤ 10 ⁵ ng/mL
Fenfluramine	Negative at ≤ 10 ⁵ ng/mL
Procaine (Novocain)	Negative at ≤ 10 ⁵ ng/mL
Ranitidine (Zantac)	Negative at ≤ 10 ⁵ ng/mL
D-Amphetamine	Negative at ≤ 10 ⁵ ng/mL
L-Amphetamine	Negative at ≤ 10 ⁵ ng/mL
Oxazepam	Negative at ≤ 10 ⁵ ng/mL
Morphine	Negative at ≤ 10 ⁵ ng/mL

Methamphetamine 500	Result
(D-Methamphetamine, Cutoff = 500ng/mL)	Positive at 500ng/mL
(±)-3,4-Methylenedioxy-n-ethylamphetamine (MDEA)	Positive at 20000ng/mL
DL-Methamphetamine	Positive at 1000ng/mL
p-Hydroxymethamphetamine	Positive at 16000ng/mL
(±)-3,4-Methylenedioxy-methamphetamine (MDMA)	Positive at 2000ng/mL
L-Methamphetamine	Positive at 5000ng/mL
Fenfluramine	Positive at 40000ng/mL
L-Amphetamine	Positive at 60000ng/mL
Trimethobenzamide	Negative at ≥ 10 ⁵ ng/mL
Chloroquine	Negative at ≥ 10 ⁵ ng/mL
Ephedrine	Negative at ≥ 10 ⁵ ng/mL
Procaine (Novocain)	Negative at ≥ 10 ⁵ ng/mL
Ranitidine (Zantac)	Negative at ≥ 10 ⁵ ng/mL
D-Amphetamine	Negative at ≥ 10 ⁵ ng/mL
Oxazepam	Negative at ≥ 10 ⁵ ng/mL
Morphine	Negative at ≥ 10 ⁵ ng/mL
(±)-3,4-Methylenedioxyamphetamine (MDA)	Negative at ≥ 10 ⁵ ng/mL

Morphine 2000	Result
(Morphine, Cutoff = 2000ng/mL)	Positive at 2000ng/mL
Codeine	Positive at 1000ng/mL
Ethylmorphine	Positive at 560ng/mL
Hydrocodone	Positive at 5000ng/mL
Hydromorphone	Positive at 7315ng/mL
Levorphanol	Positive at 16000ng/mL
6-Monoacetylmorphine	Positive at 1000ng/mL
Morphine 3-β-D-Glucuronide	Positive at 1300ng/mL
Thebaine	Negative at ≤ 10 ⁵ ng/mL
Norcodeine	Negative at ≤ 10 ⁵ ng/mL
Normorphine	Negative at ≤ 10 ⁵ ng/mL
Oxycodone	Negative at ≤ 10 ⁵ ng/mL
Oxymorphone	Negative at ≤ 10 ⁵ ng/mL
Procaine	Negative at ≤ 10 ⁵ ng/mL
Oxazepam	Negative at ≤ 10 ⁵ ng/mL
Methamphetamine	Negative at ≤ 10 ⁵ ng/mL

Methadone	Result
(Methadone, Cutoff = 300ng/mL)	Positive at 300ng/mL
LAAM	Positive at 10000ng/mL
Alphamethadol	Negative at ≤ 10 ⁵ ng/mL
Doxylamine	Negative at ≤ 10 ⁵ ng/mL
EDDP	Negative at ≤ 10 ⁵ ng/mL
EMDP	Negative at ≤ 10 ⁵ ng/mL

Oxycodone	Result
(Oxycodone, Cutoff = 100ng/mL)	Positive at 100ng/mL
Dihydrocodeine	Positive at 50,000ng/mL
Hydrocodone	Positive at 10,000ng/mL
Heroin	Negative at ≤ 10 ⁵ ng/mL
Morphine 3-β-D-Glucuronide	Negative at ≤ 10 ⁵ ng/mL
Codeine	Negative at ≤ 10 ⁵ ng/mL
Hydromorphone	Negative at ≤ 10 ⁵ ng/mL

Morphine	Negative at ≤ 10 ⁵ ng/mL
Acetylmorphine	Negative at ≤ 10 ⁵ ng/mL
Buprenorphine	Negative at ≤ 10 ⁵ ng/mL
Ethylmorphine	Negative at ≤ 10 ⁵ ng/mL

Phencyclidine	Result
(Phencyclidine, Cutoff = 25ng/mL)	Positive at 25ng/mL
Phencyclidine Morpholine	Positive at 625ng/mL
4-Hydroxyphencyclidine	Positive at 250ng/mL

Propoxyphene	Result
(Propoxyphene, Cutoff = 300ng/mL)	Positive at 300ng/mL
D-Norpropoxyphene	Positive at 1500ng/mL

Butalbital	Result
(Butalbital, Cutoff = 300ng/mL)	Positive at 300ng/mL
Secobarbital	Positive at 1500ng/mL
Amobarbital	Positive at 3000ng/mL
Alphenal	Positive at 250ng/mL
Aprobarbital	Positive at 200ng/mL
Allobarbital	Positive at 500ng/mL
Butabarbital	Positive at 1000ng/mL
Butethal	Positive at 500ng/mL
Cyclopentobarbital	Positive at 300ng/mL
Pentobarbital	Positive at 1300ng/mL
Phenobarbital	Positive at 1900ng/mL

Buprenorphine	Result
(Buprenorphine, Cutoff = 10ng/mL)	Positive at 10ng/mL
Buprenorphine-3-D-Glucuronide	Positive at 15ng/mL
Norbuprenorphine	Positive at 40ng/mL
Norbuprenorphine-3-D-Glucuronide	Positive at 500ng/mL
Morphine	Negative at ≤ 10 ⁵ ng/mL
Oxymorphone	Negative at ≤ 10 ⁵ ng/mL
Hydromorphone	Negative at ≤ 10 ⁵ ng/mL

Morphine 300	Result
(Morphine, Cutoff = 300ng/mL)	Positive at 300ng/mL
6-Acetylmorphine	Positive at 750ng/mL
Codeine	Positive at 300ng/mL
Ethyl Morphine	Positive at 200ng/mL
Heroin	Positive at 700ng/mL
Hydromorphone	Positive at 4000ng/mL
Hydrocodone	Positive at 2000ng/mL
Levorphanol	Positive at 12000ng/mL
Thebaine	Positive at 90000ng/mL
Methyprylon	Positive at 4000ng/mL
Morphine-3-β-D-Glucuronide	Positive at 450ng/mL
Oxycodone	Negative at ≤ 10 ⁵ ng/mL
Procaine	Negative at ≤ 10 ⁵ ng/mL

2-Ethylidene-1,5-Dimethyl-3,3-Diphenylpyrrolidine	Result
(2-Ethylidene-1,5-Dimethyl-3,3-Diphenylpyrrolidine, Cutoff = 300ng/mL)	Positive at 300ng/mL
2-Ethyl-5-Methyl-3,3-Diphenylpyrrolidine (EMDP)	Negative at ≤ 10 ⁵ ng/mL
Disopyramide	Negative at ≤ 10 ⁵ ng/mL
Methadone	Negative at ≤ 10 ⁵ ng/mL
Levo-α-Acetylmethadol (LAAM) HCl	Negative at ≤ 10 ⁵ ng/mL
Alphamethadol	Negative at ≤ 10 ⁵ ng/mL
Doxylamine	Negative at ≤ 10 ⁵ ng/mL

Methylenedioxy-methamphetamine	Result
(Methylenedioxy-methamphetamine, Cutoff = 500ng/mL)	Positive at 500ng/mL
3,4-Methylenedioxyamphetamine HCl (MDA)	Positive at 8000ng/mL
3,4-Methylenedioxyethylamphetamine (MDEA)	Positive at 1000ng/mL
(-)-ψ-Ephedrine	Positive at 40000ng/mL
D-Methamphetamine	Negative at ≤ 10 ⁵ ng/mL
D-Amphetamine	Negative at ≤ 10 ⁵ ng/mL
L-Amphetamine	Negative at ≤ 10 ⁵ ng/mL
L-Methamphetamine	Negative at ≤ 10 ⁵ ng/mL

Nortriptyline	Result
(Nortriptyline, Cutoff = 1000ng/mL)	Positive at 1000ng/mL
Amitriptyline	Positive at 1500ng/mL
Clomipramine	Positive at 15000ng/mL
Desipramine	Positive at 1000ng/mL
Doxepin	Positive at 2000ng/mL
Imipramine	Positive at 600ng/mL
Nordoxepin	Positive at 1000ng/mL
Promazine	Positive at 24000ng/mL
Trimipramine	Positive at 4000ng/mL
Cyclobenzaprine Hydrochloride	Positive at 1500ng/mL
Maprotiline	Negative at ≤ 10 ⁵ ng/mL
Promethazine	Negative at ≤ 10 ⁵ ng/mL
Nordomipramine	Negative at ≤ 10 ⁵ ng/mL

EFFECT OF URINARY SPECIFIC GRAVITY

Urine samples of normal, high, and low specific gravity ranges (1.000 - 1.035) were spiked with drugs at 25% below and 25% above cut-off levels respectively. The **One-Step Drug of Abuse Dip Card Test** was tested using twelve drug-free urine and spiked urine samples. The results demonstrate that varying ranges of urinary specific gravity do not affect the test results.

EFFECT OF URINARY PH

The pH of an aliquot of negative urine pool was adjusted to pH ranges of 4.0 - 9.0 and spiked with drugs at 25% below and 25% above cut-off levels. The spiked, pH-adjusted urine was tested with the **One-Step Drug of Abuse Dip Card Test**. The results demonstrate that varying ranges of pH do not interfere with the performance of the test.

Non-Cross-Reacting Compounds

Acetaminophen	β-Estradiol	Oxalic acid
Acetophenetidin	Erythromycin	Oxolinic acid
N-Acetylprocainamide	Ethanol (1%)	Oxymetazoline
Acetylsalicylic acid	Fenoprofen	Papaverine
Albumin (100mg/dL)	Furosemide	Penicillin G
Aminopyrine	Gentisic acid	Perphenazine
Amoxicillin	Hemoglobin	Phenelzine
Ampicillin	Hydralazine	Prednisone
Apomorphine	Hydrochlorothiazide	(±)-Propranolol
Ascorbic acid	Hydrocortisone	Pseudoephedrine
Aspartame	O-Hydroxyhippuric acid	Quinine
Atropine	3-Hydroxytyramine	Ranitidine
Benzilic acid	Ibuprofen	Salicylic acid
Benzoic acid	Isoproterenol	Serotonin (5- Hydroxytyramine)
Bilirubin	Isoxsuprine	Sulfamethazine
Chloral hydrate	Ketamine	Sulindac
Chloramphenicol	Ketoprofen	Tetrahydrocortisone 3-(β-Dglucuronide)
Chlorothiazide	Labetalol	Tetrahydrocortisone 3-acetate
Chlorpromazine	Loperamide	Tetrahydrozoline
Cholesterol	Meperidine	Thiamine
Clonidine	Meprobamate	Thioridazine
Cortisone	Methoxyphenamine	Triamterene
(-)-Cotinine	Nalidixic acid	Trifluoperazine
Creatinine	Naloxone	Trimethoprim
Deoxycorticosterone	Naltrexone	DL-Tryptophan
Dextromethorphan	Naproxen	Tyramine
Diclofenac	Niacinamide	DL-Tyrosine
Diffunisal	Nifedipine	Uric acid
Digoxin	Norethindrone	Verapamil
Diphenhydramine	Noscapine	Zomepirac
Ecgonine methyl ester	(±)-Octopamine	

LAY USER

A lay user study was performed at three intended user sites with 140 laypersons for each drug device. They had diverse educational and professional backgrounds and ranged in age from 21 to >50. Urine samples were prepared at the following concentrations; negative, +/-75%, +/-50%, +/-25% of the cutoff by spiking drug(s) into drug free-pooled urine specimens. The concentrations of the samples were confirmed by GC/MS. Each sample was aliquoted into individual containers and blind-labeled. Each participant was provided with the package insert, 1 blind labeled sample and a device. The results are summarized below.

% of Cutoff	Number of Samples	D-Amphetamine 1000 Concentration by GC/MS (ng/mL)	Lay Person Results		The Percentage Agreement (%)
			No. of Positive	No. of Negative	
-100% Cutoff	20	0	0	20	100%
-75% Cutoff	20	246	0	20	100%
-50% Cutoff	20	492	0	20	100%
-25% Cutoff	20	738	1	19	95%
+25% Cutoff	20	1268	18	2	90%
+50% Cutoff	20	1521	20	0	100%
+75% Cutoff	20	1775	20	0	100%

% of Cutoff	Number of Samples	D-Amphetamine 500 Concentration by GC/MS (ng/mL)	Lay Person Results		The Percentage Agreement (%)
			No. of Positive	No. of Negative	
-100% Cutoff	20	0	0	20	100%
-75% Cutoff	20	130	0	20	100%
-50% Cutoff	20	245	0	20	100%
-25% Cutoff	20	374	1	19	95%
+25% Cutoff	20	649	20	0	100%
+50% Cutoff	20	768	20	0	100%
+75% Cutoff	20	857	20	0	100%
+100% Cutoff	20	1019	20	0	100%

% of Cutoff	Number of Samples	Benzoylcgonine 300 Concentration by GC/MS (ng/mL)	Lay Person Results		The Percentage Agreement (%)
			No. of Positive	No. of Negative	
-100% Cutoff	20	0	0	20	100%
-75% Cutoff	20	71	0	20	100%
-50% Cutoff	20	142.5	0	20	100%
-25% Cutoff	20	213.8	3	17	85%
+25% Cutoff	20	379	19	1	95%
+50% Cutoff	20	454.5	20	0	100%
+75% Cutoff	20	530	20	0	100%

% of Cutoff	Number of Samples	Benzoylcgonine 150 Concentration by GC/MS (ng/mL)	Lay Person Results		The Percentage Agreement (%)
			No. of Positive	No. of Negative	
-100% Cutoff	20	0	0	20	100%
-75% Cutoff	20	37	0	20	100%
-50% Cutoff	20	73	0	20	100%
-25% Cutoff	20	109	0	20	100%
+25% Cutoff	20	178	18	2	90%
+50% Cutoff	20	223	20	0	100%
+75% Cutoff	20	258	20	0	100%
+100% Cutoff	20	301	20	0	100%

% of Cutoff	Number of Samples	11-nor-Δ ⁹ -THC-9-COOH Concentration by GC/MS (ng/mL)	Lay Person Results		The Percentage Agreement (%)
			No. of Positive	No. of Negative	
-100% Cutoff	20	0	0	20	100%
-75% Cutoff	20	12	0	20	100%
-50% Cutoff	20	24.5	0	20	100%
-25% Cutoff	20	36.8	1	19	95%
+25% Cutoff	20	64	20	0	100%
+50% Cutoff	20	77	20	0	100%
+75% Cutoff	20	90	20	0	100%

% of Cutoff	Number of Samples	Oxazepam Concentration by GC/MS (ng/mL)	Lay person results		The percentage agreement (%)
			No. of Positive	No. of Negative	
-100% Cutoff	20	0	0	20	100%
-75% Cutoff	20	76	0	20	100%
-50% Cutoff	20	145	0	20	100%
-25% Cutoff	20	222	0	20	100%
+25% Cutoff	20	384	18	2	90%
+50% Cutoff	20	468	20	0	100%
+75% Cutoff	20	542	20	0	100%

% of Cutoff	Number of Samples	Methamphetamine 1000 Concentration by GC/MS (ng/mL)	Lay Person Results		The Percentage Agreement (%)
			No. of Positive	No. of Negative	
-100% Cutoff	20	0	0	20	100%
-75% Cutoff	20	245	0	20	100%
-50% Cutoff	20	488	0	20	100%
-25% Cutoff	20	729	0	20	100%
+25% Cutoff	20	1212	19	1	95%
+50% Cutoff	20	1441	20	0	100%
+75% Cutoff	20	1666	20	0	100%

% of Cutoff	Number of Samples	Methamphetamine 500 Concentration by GC/MS (ng/mL)	Lay Person Results		The Percentage Agreement (%)
			No. of Positive	No. of Negative	
-100% Cutoff	20	0	0	20	100%
-75% Cutoff	20	129	0	20	100%
-50% Cutoff	20	259	0	20	100%
-25% Cutoff	20	393	1	19	95%
+25% Cutoff	20	669	20	0	100%
+50% Cutoff	20	730	20	0	100%
+75% Cutoff	20	930	20	0	100%
+100% Cutoff	20	1028	20	0	100%

% of Cutoff	Number of Samples	Morphine 2000 Concentration by GC/MS (ng/mL)	Lay Person Results		The Percentage Agreement (%)
			No. of Positive	No. of Negative	
-100% Cutoff	20	0	0	20	100%
-75% Cutoff	20	527	0	20	100%
-50% Cutoff	20	1053	0	20	100%
-25% Cutoff	20	1573	1	19	95%
+25% Cutoff	20	2652	20	0	100%
+50% Cutoff	20	3254	20	0	100%
+75% Cutoff	20	3711	20	0	100%

% of Cutoff	Number of Samples	Methadone Concentration by GC/MS (ng/mL)	Lay Person Results		The Percentage Agreement (%)
			No. of Positive	No. of Negative	
-100% Cutoff	20	0	0	20	100%
-75% Cutoff	20	74	0	20	100%
-50% Cutoff	20	148	0	20	100%
-25% Cutoff	20	222	2	18	90%
+25% Cutoff	20	378	19	1	95%
+50% Cutoff	20	452	20	0	100%
+75% Cutoff	20	530	20	0	100%

% of Cutoff	Number of Samples	Oxycodone Concentration by GC/MS (ng/mL)	Lay Person Results		The Percentage Agreement (%)
			No. of Positive	No. of Negative	
-100% Cutoff	20	0	0	20	100%
-75% Cutoff	20	24	0	20	100%
-50% Cutoff	20	49	0	20	100%
-25% Cutoff	20	74	1	19	95%
+25% Cutoff	20	124	19	1	95%
+50% Cutoff	20	148	20	0	100%
+75% Cutoff	20	173	20	0	100%

% of Cutoff	Number of Samples	Phencyclidine Concentration by GC/MS (ng/mL)	Lay Person Results		The Percentage Agreement (%)
			No. of Positive	No. of Negative	
-100% Cutoff	20	0	0	20	100%
-75% Cutoff	20	6	0	20	100%
-50% Cutoff	20	12.2	0	20	100%
-25% Cutoff	20	19	0	20	100%
+25% Cutoff	20	31.3	19	1	95%
+50% Cutoff	20	37	20	0	100%
+75% Cutoff	20	44	20	0	100%

% of Cutoff	Number of Samples	Propoxyphene Concentration by GC/MS (ng/mL)	Lay Person Results		The Percentage Agreement (%)
			No. of Positive	No. of Negative	
-100% Cutoff	20	0	0	20	100%
-75% Cutoff	20	73	0	20	100%
-50% Cutoff	20	154	0	20	100%
-25% Cutoff	20	219	1	19	95%
+25% Cutoff	20	363	20	0	100%
+50% Cutoff	20	437	20	0	100%
+75% Cutoff	20	518	20	0	100%

% of Cutoff	Number of Samples	Butalbital Concentration by GC/MS (ng/mL)	Lay Person Results		The Percentage Agreement (%)
			No. of Positive	No. of Negative	
-100% Cutoff	20	0	0	20	100%
-75% Cutoff	20	77	0	20	100%
-50% Cutoff	20	156	0	20	100%
-25% Cutoff	20	234	1	19	95%
+25% Cutoff	20	390	19	1	95%
+50% Cutoff	20	468	20	0	100%
+75% Cutoff	20	547	20	0	100%

% of Cutoff	Number of Samples	Buprenorphine Concentration by GC/MS (ng/mL)	Lay Person Results		The Percentage Agreement (%)
			No. of Positive	No. of Negative	
-100% Cutoff	20	0	0	20	100%
-75% Cutoff	20	2.6	0	20	100%
-50% Cutoff	20	5.2	0	20	100%
-25% Cutoff	20	7.8	0	20	100%
+25% Cutoff	20	13	19	1	95%
+50% Cutoff	20	15.7	20	0	100%
+75% Cutoff	20	18.3	20	0	100%

% of Cutoff	Number of Samples	Morphine 300 Concentration by GC/MS (ng/mL)	Lay Person Results		The Percentage Agreement (%)
			No. of Positive	No. of Negative	
-100% Cutoff	20	0	0	20	100%
-75% Cutoff	20	74	0	20	100%
-50% Cutoff	20	148	0	20	100%
-25% Cutoff	20	228	1	19	95%
+25% Cutoff	20	379	20	0	100%
+50% Cutoff	20	443	20	0	100%
+75% Cutoff	20	516	20	0	100%

% of Cutoff	Number of Samples	EDDP Concentration by GC/MS (ng/mL)	Lay Person Results		The Percentage Agreement (%)
			No. of Positive	No. of Negative	
-100% Cutoff	20	0	0	20	100%
-75% Cutoff	20	81	0	20	100%
-50% Cutoff	20	157	0	20	100%
-25% Cutoff	20	235	2	18	90%
+25% Cutoff	20	410	20	0	100%
+50% Cutoff	20	485	20	0	100%
+75% Cutoff	20	566	20	0	100%

% of Cutoff	Number of Samples	Methylenedioxy- methamphetamine Concentration by GC/MS (ng/mL)	Lay Person Results		The Percentage Agreement (%)
			No. of Positive	No. of Negative	
-100% Cutoff	20	0	0	20	100%
-75% Cutoff	20	115	0	20	100%
-50% Cutoff	20	237	0	20	100%
-25% Cutoff	20	358	0	20	100%
+25% Cutoff	20	598	19	1	95%
+50% Cutoff	20	755	20	0	100%
+75% Cutoff	20	912	20	0	100%

% of Cutoff	Number of Samples	Nortriptyline Concentration by GC/MS (ng/mL)	Lay Person Results		The Percentage Agreement (%)
			No. of Positive	No. of Negative	
-100% Cutoff	20	0	0	20	100%
-75% Cutoff	20	261	0	20	100%
-50% Cutoff	20	495	0	20	100%
-25% Cutoff	20	720	1	19	95%
+25% Cutoff	20	1180	20	0	100%
+50% Cutoff	20	1485	20	0	100%
+75% Cutoff	20	1687	20	0	100%

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 2.Ambre J. J. Anal. Toxicol. 1985; 9:241.
 3.Hawks RL, CN Chiang. Urine Testing for Drugs of Abuse. National Institute for Drug Abuse (NIDA), Research Monograph 73, 1986.

ADDITIONAL INFORMATION AND REFERENCES
 The following list of organizations may be helpful for counseling support and resources. These groups also have an internet address which can be accessed for additional information.

National Clearinghouse for Alcohol and Drug Information www.health.org 1-800-729-6686
 Center for Substance Abuse Treatment www.health.org 1-800-662-HELP
 The National Council on Alcoholism and Drug Dependence www.ncadd.org 1-800-NCA-CALL
 American Council for Drug Education (ACDE) www.acde.org 1-800-488-DRUG

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