

One-Step Drug of Abuse Cup Test

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One-Step Drug of Abuse Cup Test is a rapid test for the qualitative detection of D-Amphetamine 1000, D-Amphetamine 500, Benzoylgonine 300, Benzoylgonine 150, 11-nor- Δ^8 -THC-9-COOH, Oxazepam, Methamphetamine 1000, Methamphetamine 500, Morphine 2000, Methadone, Phencyclidine, Oxycodone, Propoxyphene, Butalbital, Buprenorphine, Morphine 300, 2-Ethylidene-1, 5-dimethyl-3, 3-dipheylpyrrolidine, Methyleneoxymethamphetamine, 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 use 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. 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.

The test may come with adulterant tests [specimen validity tests] of (Specific Gravity (S.G.), Oxidants (OX), pH, Creatinine (CR), Nitrite (NI) and Glutaraldehyde (GL)) for the determination of diluted or adulterated urine specimens.

For *in vitro* diagnostic use only.

WHAT IS ONE-STEP DRUG OF ABUSE CUP TEST?

One-Step Drug of Abuse Cup Test is a rapid test for the qualitative detection of D-Amphetamine 1000, D-Amphetamine 500, Benzoylgonine 300, Benzoylgonine 150, 11-nor- Δ^8 -THC-9-COOH, Oxazepam, Methamphetamine 1000, Methamphetamine 500, Morphine 2000, Methadone, Oxycodone, Phencyclidine, Propoxyphene, Butalbital, Buprenorphine, Morphine 300, 2-Ethylidene-1, 5-dimethyl-3, 3-dipheylpyrrolidine, Methyleneoxymethamphetamine, and Nortriptyline in human urine. The **One-Step Drug of Abuse Cup Test** yields a positive result when drug and/or its metabolite in urine is at or exceeds its cutoff concentration.

WHAT IS THE CUTOFF VALUE AND APPROXIMATE DETECTION TIME?

Drug (Identifier)	Cutoff Level	Minimum Detection Time	Maximum Detection Time
D-Amphetamine (AMP)	1000ng/mL	4-6 hours	2-3 days
D-Amphetamine (AMP 500)	500ng/mL	4-6 hours	2-3 days
Benzoylgonine (COC)	300ng/mL	2-6 hours	2-3 days
Benzoylgonine (COC 150)	150ng/mL	2-6 hours	2-3 days
11-nor- Δ^8 -THC-9-COOH (THC)	50ng/mL	1-3 hours	1-7 days
Oxazepam (BZO)	300ng/mL	2-7 hours	1-4 days
Methamphetamine (mAMP)	1000ng/mL	4-6 hours	2-3 days
Methamphetamine (mAMP 500)	500ng/mL	4-6 hours	2-3 days
Morphine (OPI)	2000ng/mL	2-6 hours	1-3 days
Methadone (MTD)	300ng/mL	3-8 hours	1-3 days
Oxycodone (OXY)	100ng/mL	1-3 hours	1-2 days
Phencyclidine (PCP)	25ng/mL	4-6 hours	7-14 days
Propoxyphene (PPX)	300ng/mL	6-12 hours	1-3 days
Butalbital (BARB)	300ng/mL	2-4 hours	1-3 weeks
Buprenorphine (BUP)	10ng/mL	2-6 hours	2-4 days
Morphine (MOR)	300ng/mL	2-6 hours	1-3 days
2-Ethylidene-1,5-dimethyl-3,3-dipheylpyrrolidine (EDDP)	300ng/mL	3-8 hours	1-3 days
Methyleneoxymethamphetamine (MDMA)	500ng/mL	2-7 hours	2-4 days
Nortriptyline (TCA)	1,000ng/mL	8-12 hours	2-7 days

PRINCIPLE

The **One-Step Drug of Abuse Cup 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.

ADULTERATION SUMMARY AND EXPLANATION OF THE TEST

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 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. Tests that detect urinary characteristics such as specific gravity, pH, oxidants, nitrite, glutaraldehyde and creatinine are considered the best ways to detect 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 acid 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 (NI): 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.

WARNINGS AND PRECAUTIONS

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

CONTENT OF THE PACKAGE

Included in package:

- User Instruction
- Test Cup (inside foil pouch)
- Security Seal Label
- Color Chart Card for Adulterants Interpretation (when applicable)

Not included in package:

- Watch, Timer or Clock

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 cup 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?

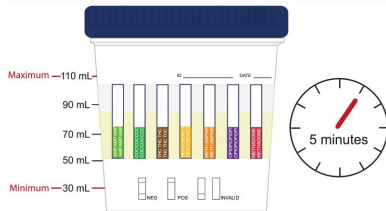
Urine from any time of day can be used. The minimum detection time varies for different drugs. (Refer to the approximate detection timetable).

HOW TO COLLECT URINE?

1. When you are ready to begin, remove the test cup from the sealed foil pouch. Peel back and remove the label from the test cup to show the drug test strips. Notice the colored tape on each strip correlates to the name of the drug you are testing for.
2. Remove the cap from the test cup. Fill the test cup with a minimum of 30 mL (see the minimum line mark) fresh urine sample. Do not over-fill (the maximum-line mark).
3. When finished, recap the test cup (be sure to tighten firmly) and place the test cup on a flat surface. Be sure **NOT** to tilt or flip it over.

HOW TO DO THE TEST?

1. After filling the test cup with a fresh urine sample, wait for 5 minutes (start timing immediately after sample is collected) and read the results. **DO NOT** read results after 5 minutes.



Note: Results after more than 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 - Drug Test area, then it indicates a Preliminary Positive result for the corresponding drug.

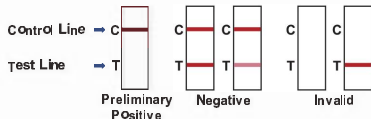
Negative(-)

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

Invalid

If at 5 minutes, NO line appears in the C - Control area, then the results are Invalid.

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 Cup 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 is not detected by **One-Step Drug of Abuse Cup Test**. If the sample is diluted, or if the sample is tainted or contaminated with a substance this could cause false negative results.

READING THE ADULTERANT RESULTS

(Please refer to the color chart card)

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.

TEST LIMITATIONS

1. The **One-Step Drug of Abuse Cup 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.
2. There is a possibility that interfering substances in the urine specimen may cause erroneous results.
3. Substances, such as bleach and/or alum, in urine specimens may produce erroneous results.
4. A positive result does not indicate intoxication, 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 cutoff 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.

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 > 20mg/dL may produce false positive glutaraldehyde results.
5. Glutaraldehyde: Glutaraldehyde is normally not 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: Creatinine tests for the specimen for dilution and flushing. Normal creatinine levels are between 20 and 350mg/dL. Under rare conditions, certain kidney diseases may show dilute urine.

QUALITY CONTROL

If you work in a laboratory, you should perform quality control testing and you should read this section. A procedural control is included in the test. A color line appearing in the control region (C) is considering 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 test cup.

PERFORMANCE CHARACTERISTICS

Eighty clinical urine specimens were analyzed by GC/MS and by the **One-Step Drug of Abuse Cup 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	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	12	26
Negative	10	10	19	2	0

% agreement among positives is 95%

% 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	0	13	26
Negative	10	10	20	1	0

% agreement among positives is 97.5%

% agreement among negatives is 100%

From the results of the above tables, the total results are shown as below for D-Amphetamine 1000: The average positive agreement is 96.7%. The average negative agreement is 98.3%.

Viewer A:

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

Viewer B:

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

Viewer C:

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

Accuracy – Benzoylecgonine 300

100

% agreement among negatives is 97.5%

[illegible]

% agreement among negatives is 100%

100

From the results of the above tables, the

Viewer A:

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

Viewer B:

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

Viewer C:

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

Accuracy - 11-nor- Δ^9 -THC-9-COOH

100

% agreement among negatives is 97.5%

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100% agreement among negatives is 100%

100

From the results of the above tables, the

Viewer A

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

Viewer B

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

Viewer C

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

Accuracy—Methamphetamine 1000

1

% agreement among negatives is 100%

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Mineral Co.

100

From the results of the above tables, the

Viewer A:

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

Viewer B:

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

Viewer C:

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

Accuracy - Morphine 2000

Viewer A:

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

Viewer B:

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

Viewer C:

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

Viewer A:

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

Viewer B:

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

Viewer C:

% agreement among positives is 95%
% agreement among negatives is 97.5%

Accuracy - Oxycodone

Viewer A:

% agreement among positives is 95%
% agreement among negatives is 97.5%

Viewer B

% agreement among positives is 97.5%
% agreement among negatives is 95%

Viewer C

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

Viewer A:

% agreement among positives is 97.5%
% agreement among negatives is 95%

Viewer B

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

Viewer C:

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

Accuracy - Propoxyphene

Accuracy
Viewer A:

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

viewer B:

% agreement among negatives is 97.5%

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From the results of the above tables, the

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	2/48
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	1/49
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 - Benzoylcegonine 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	3/47
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 - Benzoylcegonine 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	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	3/47
375	50	0/50
450	50	0/50
525	50	0/50
600	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	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 - 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	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	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	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	2/48
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	2/48
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	3/47
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	3/47
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	3/47
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	2/48
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	3/47
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	3/47
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	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 - 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	2/48
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 - 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	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	3/47
375	50	0/50
450	50	0/50
525	50	0/50
600	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	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	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	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 - 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	2/48
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 - 11-nor- Δ^9 -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	2/48
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	1/49
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	2/48
62.5	50	0/50
75	50	0/50
87.5	50	0/50
100	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	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	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	3/47
375	50	0/50
450	50	0/50
525	50	0/50
600	50	0/50

SPECIFICITY AND CROSS REACTIVITY

To test the specificity of the test, the test device was used to test Amphetamine 1000, Amphetamine 500, Cocaine 300, Cocaine 150, Marijuana, Benzodiazepine, Methamphetamine 1000, Methamphetamine 500, Opiates 2000, Methadone, Phencyclidine, Oxycodone, Barbiturate, Buprenorphine, Opiates 300, 2-Ethylidene-1, 5-Dimethyl-3, 3-Diphenylpyrrolidine, Propoxyphene, Methylenedioxy-methamphetamine, Tricyclic Antidepressants, 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.

Amphetamine 1000	Result
(D-Amphetamine, Cutoff= 1000ng/mL)	Positive at 1000ng/mL
L-Amphetamine	Positive at 100000ng/mL
DL-Amphetamine	Positive at 500ng/mL
(+/-)-3,4-Methylenedioxyamphetamine (MDA)	Positive at 1300ng/mL
Phentermine	Positive at 100000ng/mL
Apomorphine	Positive at 50000ng/mL
β-Phenylethylamine	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

Amphetamine 500	Result
(D-Amphetamine, Cutoff= 500 ng/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 ≤ 10 ⁵ ng/mL
D-Methamphetamine	Negative at ≤ 10 ⁵ ng/mL
L-Methamphetamine	Negative at ≤ 10 ⁵ ng/mL
(±)-Methamphetamine	Negative at ≤ 10 ⁵ ng/mL
Ephedrine	Negative at ≤10 ⁵ ng/mL
3,4-Methylenedioxy-N-ethylamphetamine (MDE)	Negative at ≤ 10 ⁵ ng/mL
3,4-Methylenedioxy-methamphetamine (MDMA)	Negative at ≤ 10 ⁵ ng/mL
Phentermine	Negative at ≤ 10 ⁵ ng/mL

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

Cocaine 150	Result
(Benzoylcegonine, Cutoff = 150ng/mL)	Positive at 150ng/mL
Cocaine Hydrochloride	Positive at 3000ng/mL
Norcocaine	Negative at ≤ 10 ⁵ ng/mL
Cocacethylene	Negative at ≤ 10 ⁵ ng/mL
Ecgonine	Negative at ≤ 10 ⁵ ng/mL

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

Benzodiazepine	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
Debrazepam	Positive at 1560ng/mL
Desalkylflurazepam	Positive at 1565ng/mL
Diazepam	Positive at 115ng/mL
Estazolam	Positive at 165ng/mL
Flunitrazepam	Positive at 166ng/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 2500 ng/mL
DL-Lorazepam	Negative at ≤ 10 ⁵ ng/mL
Methamphetamine	Negative at ≤ 10 ⁵ ng/mL
Morphine	Negative at ≤ 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-Methylenedioxymethamphetamine (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 (Novocaine)	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
Benzodiazepine	Negative at ≤ 10 ⁵ ng/mL
Morphine	Negative at ≤ 10 ⁵ ng/mL

Methamphetamine 500	Result
(D-Methamphetamine, Cutoff= 500 ng/mL)	Positive at 500ng/mL
(±)3,4-Methylenedioxy-n-ethylamphetamine (MDEA)	Positive at 20000ng/mL
(±)-Methamphetamine	Positive at 1000ng/mL
p-Hydroxymethamphetamine	Positive at 16000ng/mL
(±)3,4-MDMA	Positive at 2000ng/mL
L-Methamphetamine	Positive at 5000ng/mL
Fenfluramine	Positive at 40000ng/mL
L-Amphetamine	Positive at 60000ng/mL
D-Pseudoephedrine	Negative at ≤ 10 ⁵ ng/mL
Trimethobenzamide	Negative at ≤ 10 ⁵ ng/mL
Chloroquine	Negative at ≤ 10 ⁵ ng/mL
Ephedrine	Negative at ≤ 10 ⁵ ng/mL
Procaine (Novocaine)	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-MDA	Negative at ≤ 10 ⁵ ng/mL

Opiates 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
Levo-α-Acetylmethadol	Positive at 10000ng/mL
Alphamethadol	Negative at ≤ 10 ⁵ ng/mL
Doxylamine	Negative at ≤ 10 ⁵ ng/mL
2-Ethylidene-1, 5-Dimethyl-3,3-Diphenylpyrrolidine	Negative at ≤ 10 ⁵ ng/mL
2-Ethyl-5-Methyl-3,3-Diphenylpyrrolone	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

Barbiturate	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
Alobarbital	Positive at 500ng/mL
Butabarbital	Positive at 1000ng/mL
Butehal	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

Opiates 300	Result
(Morphine, Cutoff= 300ng/mL)	Positive at 300ng/mL
6-Acetylmorphine	Positive at 750ng/mL
Codeine	Positive at 300ng/mL
Ethylmorphine	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
Methypylon	Positive at 4000ng/mL
Morphine-3-β-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 Hydrochloride (LAAM)	Negative at ≤ 10 ⁵ ng/mL
Alphamethadol	Negative at ≤ 10 ⁵ ng/mL
Doxylamine	Negative at ≤ 10 ⁵ ng/mL

Methylenedioxymethamphetamine	Result
(Methylenedioxymethamphetamine, Cutoff= 500ng/mL)	Positive at 500ng/mL
3,4-Methylenedioxymethamphetamine HCl (MDA)	Positive at 8000ng/mL
3,4-Methylenedioxymethylamphetamine (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

Tricyclic Antidepressants	Result
(Nortriptyline, Cutoff= 1000ng/mL)	Positive at 1000ng/mL
Amiripityline	Positive at 5000ng/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
Norclomipramine	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 cutoff levels respectively. **One-Step Drug of Abuse Cup 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 **One-Step Drug of Abuse Cup 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	Genisic 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	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	2	18	90%
+25% Cutoff	20	1268	19	1	95%
+50% Cutoff	20	1521	20	0	100%
+75% Cutoff	20	1775	20	0	100%

% of Cutoff	Number of Samples	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	Cocaine 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	2	18	90%
+25% Cutoff	20	379	20	0	100%
+50% Cutoff	20	454.5	20	0	100%
+75% Cutoff	20	530	20	0	100%

% of Cutoff	Number of Samples	Cocaine 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	1	19	95%
+25% Cutoff	20	178	20	0	100%
+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	Marijuana 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	19	1	95%
+50% Cutoff	20	77	20	0	100%
+75% Cutoff	20	90	20	0	100%

% of Cutoff	Number of Samples	Benzodiazepine Concentration by GC/MS (ng/mL)	Lay Person Results		The Percentage Agreement(%)
			No. of Positive	No. of Positive	
-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	2	18	90%
+25% Cutoff	20	384	20	0	100%
+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	19	1	95%
+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	Opiates 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	0	20	100%
+25% Cutoff	20	2652	19	1	95%
+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	1	19	95%
+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	18	2	90%
+50% Cutoff	20	37	20	0	100%
+75% Cutoff	20	44	20	0	100%

% of Cutoff	Number of Samples	Barbiturate 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	20	0	100%
+50% Cutoff	20	468	20	0	100%
+75% Cutoff	20	547	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	0	20	100%
+25% Cutoff	20	363	19	1	95%
+50% Cutoff	20	437	20	0	100%
+75% Cutoff	20	518	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	1	19	95%
+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	Opiates 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	0	20	100%
+25% Cutoff	20	379	19	1	95%
+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	1	19	95%
+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 Positive	
-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	1	19	95%
+25% Cutoff	20	598	20	0	100%
+50% Cutoff	20	755	20	0	100%
+75% Cutoff	20	912	20	0	100%

% of Cutoff	Number of Samples	Tricyclic Antidepressants Concentration by GC/MS (ng/mL)	Lay Person Results		The Percentage Agreement(%)
			No. of Positive	No. of Positive	
-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	19	1	95%
+50% Cutoff	20	1485	20	0	100%
+75% Cutoff	20	1687	20	0	100%

BIBLIOGRAPHY OF SUGGESTED READING

1. Stewart DJ, Inaba T, Lucassen M, Kalow W. Clin. Pharmacol. Ther. April 1979; 25 ed: 464, 264-8.
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 to you for counseling support and resources. These groups also have an Internet address, which can be access 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

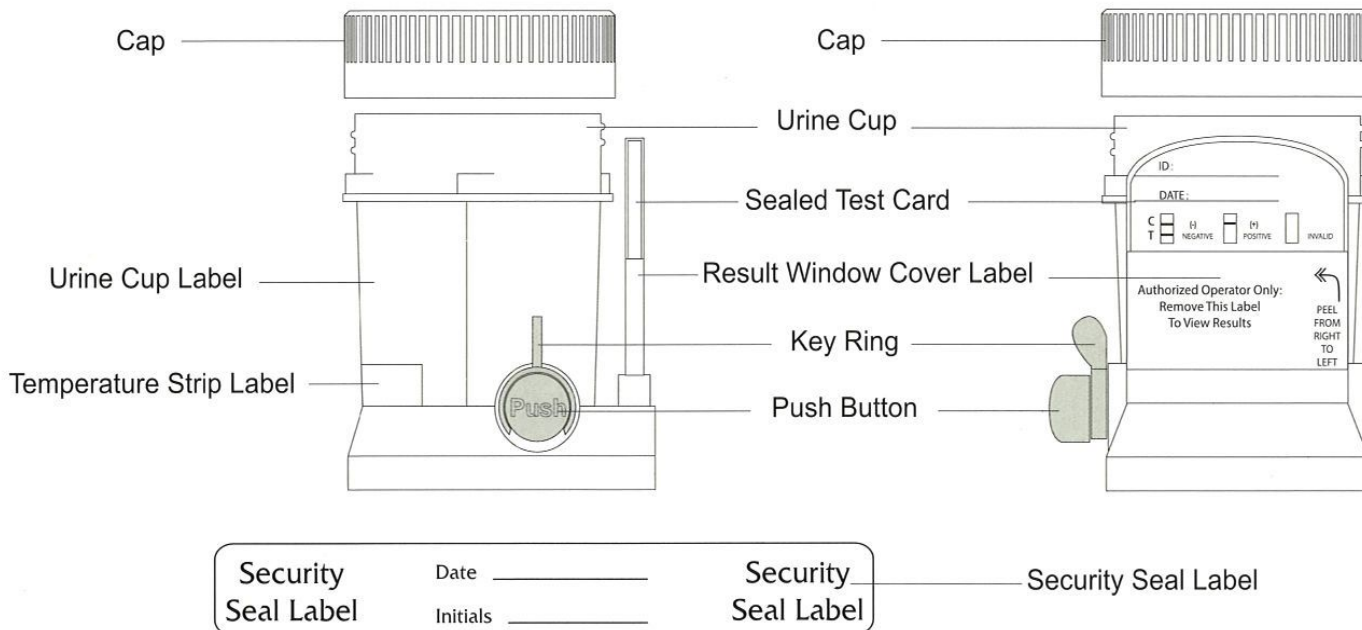
The National Council on Alcoholism and Drug Dependence www.ncadd.org 1-800-NCA-CALL

American Council for Drug Education (ACDE) www.acde.org 1-800-488-DRUG

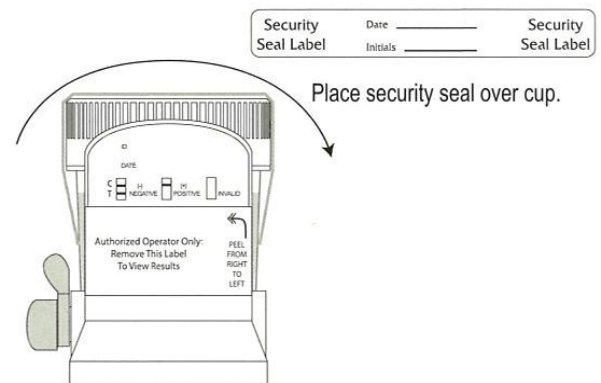
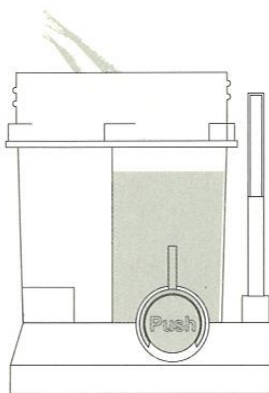
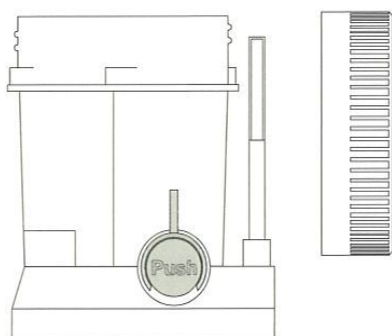
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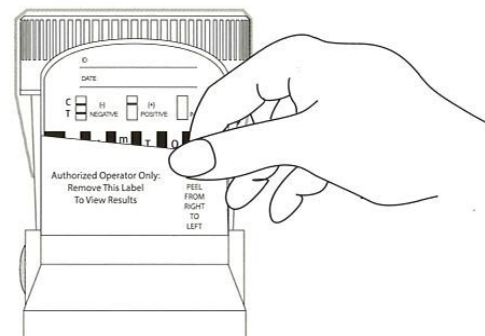
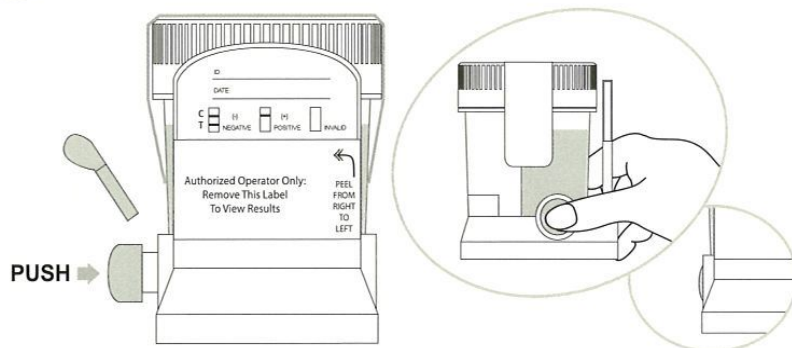
Built In Key Cup



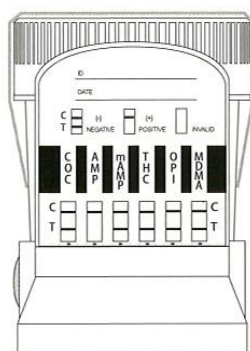
- 1 Remove Cap.
- 2 Donor provides specimen.
- 3 Replace and secure cap. Technician dates and initials the security seal label and places it over cap.



- 4 On a flat surface, remove the key ring and push the button.
- 5 Peel off the result window cover label.



- 6 Test is read at result window.



Negative results can be read as soon as they appear.
Read positive results at 5 minutes.
DO NOT INTERPRET RESULT AFTER 5 MINUTES.



All positive results are presumptive and should be confirmed by an alternative method (e.g. GC/MS).
A photocopy of the results can be made by placing the entire sealed cup with the card face down on the copier.