One Step Methamphetamine Urine Test

One Step Methamphetamine Urine Test is a rapid one step test for the qualitative detection of Methamphetamine and its principal metabolites in human urine at specified cut-off level.
For in vitro diagnostic use only. For professional use only.

INTENDED USE

One Step Methamphetamine Urine Test is a lateral flow chromatographic immunoassay for the detection of Methamphetamine in human urine at the cut-off concentration of 1000 ng/ml. This assay provides only a qualitative, preliminary analytical test result. A more specific alternate chemical method must be used in order to obtain a confirmed analytical result. Gas chromatography/mass spectrometry (GC/MS) is the preferred confirmatory method. Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are used.

SUMMARY

Methamphetamine is a potent sympathomimetic agent with therapeutic applications. Acute higher doses lead to enhanced stimulation of the central nervous system and induce euphoria, alertness, and a sense of increased energy and power. More acute responses produce anxiety, paranoia, psychotic behavior, and cardiac dysrhythmias. The pattern of psychosis which may appear at half-life of about 15 hours and is excreted in urine as amphetamine and oxidized as deaminated and hydroxylated derivatives. However, 40% of methamphetamine is excreted unchanged. Thus the presence of the parent compound in the urine indicates methamphetamine use.

PRINCIPLE

One Step Methamphetamine Urine Test is a competitive immunoassay that is used to screen for the presence of Methamphetamine in urine. It is chromatographic absorbent device in which Methamphetamine and its principal metabolites metabolites in a sample competitively combined to a limited number of anti-D-Methamphetamine monoclonal antibody (mouse) conjugate binding sites.
When add four drops of the urine specimen to the sample well, the urine is absorbed into the device by capillary action, mixes with the Methamphetamine monoclonal antibody conjugate, and flows across the pre-coated membrane. When sample drug levels are zero or below the target cut off (the detection sensitivity of the test), anti-D-Methamphetamine monoclonal antibody (mouse) conjugate binds to the Methamphetamine -protein (duck egg) conjugate immobilized in the Test Region (T) of the device. This produces a colored Test line that, regardless of its intensity, indicates a negative result.
When sample drug levels are at or above the target cutoff, the free drug in the sample binds to the Methamphetamine monoclonal antibody conjugate preventing the Methamphetamine monoclonal antibody conjugate from binding to the Methamphetamine protein conjugate immobilized in the Test Region (T) of the device. This prevents the development of a distinct colored band in the test region, indicating a potentially positive result.
To serve as a procedure control, a colored line will appear at the Control Region (C), where the Goat anti mouse IgG polyclonal antibody immobilized in, if the test has been performed properly.

WARNINGS AND PRECAUTIONS

1. This kit is for external use only. Do not swallow.
2. Discard after first use. The test cannot be used more than once.
3. Do not use test kit beyond expiry date.
4. Do not use the kit if the pouch is punctured or not well sealed.
5. Keep out of the reach of children.
6. Do not read after 5 minutes.
7. This kit is for in vitro diagnostic use.

CONTENT OF THE KIT

1. 25 tests per kit., one test in one pouch.
2. One pouch containing a test and a desiccant. The only desiccant is for storage purposes only, and is not used in the test procedures.
3. Leaflet with instructions for use.
4. Dropper.

STORAGE AND STABILITY

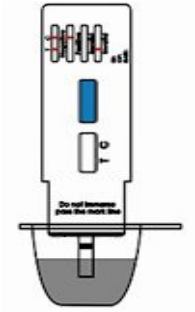
Store at 4 ~ 30 ºC in the sealed pouch up to the expiration date.
Keep away from direct sunlight, moisture and heat.
DO NOT FREEZE.

SPECIMEN COLLECTION AND PREPARATION

Collect a urine sample in the supplied urine cup. Urine specimens may be refrigerated (2-8°C) and stored up to forty-eight hours. For longer storage, freeze the samples (-20°C or below).
Bring frozen or refrigerated samples to room temperature before testing. Previously frozen or refrigerated samples should be well mixed before analysis. Cloudy specimens should be centrifuged before analysis. Use only clear aliquots for testing.

TEST PROCEDURE

Test must be in room temperature (18ºC to30º C)
1. Open the sealed pouch by tearing along the notch. Remove the test device from the pouch.
2. Hold the one side of the device with one hand. Use the other hand to pull out the cap and expose the absorbent end.
3. Immerse the absorbent end into the urine sample about 10 seconds. Make sure that the urine level is not above the “MAX” line printed on the front of the device.
4. Lay the device flat on a clean, dry, non-absorbent surface.
5. Read the result at 5 minutes. **Do not read after 5 minutes.**



INTERPRETATION OF RESULTS

Positive (+)

A rose-pink band is visible in the control region. No color band appears in the appropriate test region. It indicates a positive result for the corresponding drug of that specific test zone.

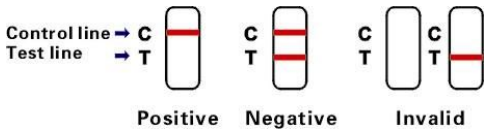
Negative (-)

A rose-pink band is visible in the control region and the appropriate test region. It indicates that the concentration of the corresponding drug of that specific test zone is below zero or the detection limit of the test.

Invalid

If a color band is not visible in the control region or a color band is only visible in the test region, the test is invalid. Another test should be run to re-evaluate the specimen. Please contact the distributor or the store, where you bought the product, with the lot number.

Note: There is no meaning attributed to line color intensity or width.



Users should follow the appropriate federal state, and local guidelines concerning the frequency of assaying external quality control materials.

Though there is an internal procedural control line in the test device of Control region, the use of external controls is strongly recommended as good laboratory testing practice to confirm the test procedure and to verify proper test performance. Positive and negative control should give the expected results. When testing the positive and negative control, the same assay procedure should be adopted.

LIMITATIONS OF PROCEDURE

1. This test has been developed for testing urine samples only. The performance of this test using other specimens has not been substantiated.

2. Adulterated urine samples may produce erroneous results. Strong oxidizing agents such as bleach (hypochlorite) can oxidize drug analytes. If a sample is suspected of being adulterated, obtain a new sample.

3. This test is a qualitative screening assay. It is not designed to determine the quantitative concentration of drugs or the level of intoxication

PERFORMANCE CHARACTERISTICS

Accuracy

Eighty clinical urine specimens were analyzed by GC-MS and by One Step Methamphetamine Test. Each test was read by three viewers. Samples were divided by concentration into four categories: less than half the cutoff, near cutoff negative, near cutoff positive, and high positive. Results were as follows:

Viewer A:

Result	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	5	19	20
Negative	26	9	1	0

% agreement among positives is 97.5% (95% Confidence Interval 82% - 100%)

% agreement among negatives is 87.5% (95% Confidence Interval 72% - 100%)

Viewer B:

Result	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	2	3	19	20
Negative	24	11	1	0

% agreement among positives is97.5% (95% Confidence Interval 82%- 100%)

% agreement among negatives is 87.5% (95% Confidence Interval 72% - 100%)

Viewer C:

Result	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	1	5	18	20
Negative	25	9	2	0

% agreement among positives is 95% (95% Confidence Interval 79.5% - 100%)

% agreement among negatives is 85%(95% Confidence Interval 69.5% - 100%)

From the results of the above tables, the total results are showed as below:
The average positive agreement is 96.7%
The average negative agreement is 86.7%

Precision and Sensitivity

To investigate the precision and sensitivity, samples were analyzed at the following concentrations: cutoff - 50%, cutoff - 25%, cutoff, cutoff +25%, and the cutoff + 50%. All concentrations were confirmed with GC-MS. Each concentration was tested using three different lots. Thirty samples were analyzed at each concentration, and each result was read by three viewers, for a total of 90 results per concentration per lot.

Lot 1

Approximate concentration of sample (ng/mL)	Number of determinations	Results Negative/ Positive
500	90	90/0
750	90	81/9
1000	90	34/56
1250	90	13/77
1500	90	0/90

Lot 2

Approximate Concentration of sample (ng/mL)	Number of determinations	Results Negative/ Positive
500	90	90/0
750	90	81/9
1000	90	34/56
1250	90	13/77
1500	90	0/90

Lot 3

Approximate Concentration of sample (ng/mL)	Number of determinations	Results Negative/ Positive
500	90	90/0
750	90	81/9
1000	90	34/56
1250	90	13/77
1500	90	0/90

Specificity and cross reactivity

To test the specificity of the test, the test device was used to test methamphetamine, its principal metabolites 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. These concentrations below also represent the limits of detection for the specified drugs or metabolites.

Component	Concentration (ng/ml)
d (+)-Methamphetamine	1,000
d-Amphetamine	50,000
l -Amphetamine	50,000
Chloroquine	50,000
(+/-)-Ephedrine	50,000
(-)-Methamphetamine	25,000
l –Methamphetamine	8,000
(+/-) 3, 4-methylenedioxumethamphetamine (MDMA)	2,000
3, 4-methylenedioxyamphetamine (MDA)	3,000
3,4-Methylenedioxyethylamphetamine (MDE)	600
β-Phenylethylamine	50,000
Trimethobenzamide	10,000

Effect of Urinary Specific Gravity

5 urine samples with density ranges (1.000-1.035) are collected and spiked with Methamphetamine at 50% below and 50% above cutoff level. One step Methamphetamine urine test was tested in duplicate. The results demonstrate that varying ranges of urinary specific gravity do not affect the test result.

Effect of Urinary PH

The pH of an aliquot negative urine pool is adjusted to a pH range of 4 to 9 in 1 pH unit increments and spiked with methamphetamine at 50% below and 50% above cutoff levels. One step Methamphetamine urine test was tested in duplicate. The result demonstrate that varying ranged of PH do not interfere with the performance of the test.

Interfering substances

Clinical urine samples may contain substances that could potentially interfere with the test. The following compounds were added to drug-free urine, urine with a methamphetamine concentration 50% below the cutoff, and urine with a methamphetamine concentration 50% above the cutoff. All potential interferents were added at a concentration of 100 µg/mL. None of the urine samples showed any deviation from the expected results.

Acetamidophen
Acetophenetidin
N-Acetylprocainamide
Acetylsalicylate
Aminopyrine
Amitryptyline
Amobarbital
Amoxicillin
Ampicillin
Apomorphine
Aspartame
Atropine
Benzilic acid
Benzoic acid
Benzoylecgonine
Benzphetamine
Butabartital
Cannabidiol
Chloralhydrate
Chloramphenicol
Chlordiazepoxide
Chlorothiazide
Chlorpromazine
Cholesterol
Clomipramine
Clonidine
Cocaine hydrochloride
Codeine
Cortisone
(-) Cotinine
Creatinine
Deoxycorticosterone
Dextromethorphan
Diazepam
Diclofenac
Methadone
Methaqualone
Methylphenidal
Methyprylon
Morphine-3-β-Dglucuronide
Nalidixic acid
Nalorphine
Naloxone
Naltrexone
Naproxen
Niacinamide
Nifedipine
Norcodein
Norethindrone
Noroxymorphone
D-Norpropoxyphene
Noscapine
Nylidrin
D,L-Octopamine
Oxalic acid
Oxazepam
Oxolinic acid
Oxycodone
Oxymetazoline
Papaverine
Penicillin-G
Pentazocine
Pentobarbital
Perphenazine
Phencyclidine
Phenelzine
Phenobarbital
Prednisolone
Phenylpropanolamine
Prednisone
Diflunisal
Digoxin
Diphenhydramine
Doxylamine
Ecgonine hydrochloride
Ecgonine methylester
Erythromycin
β-Estradiol
Estrone-3-sulfate
Ethyl-p-aminobenzoate
Fenoprofen
Furosemide
Gentisic acid
Glucuronide
Glutethimide
Guaifenesin
Hippuric acid
Hydralazine
Hydrochlorothiazide
Hydrocodone
Hydrocortisone
O-Hydroxyhippuric acid
3-Hydroxytyramine
Ibuprofen
Imipramine
(-) Isoproterenol
Isoxsuprine
Ketamine
Ketoprofen
Labetalol
Levorphanol
Loperamide
Loxapine succinate
Maprotiline
Meperidine
Meprobamate
Procaine
Promazine
Promethazine
D,L-Propanolol
D-Propoxyphene
D-Pseudoephedrine
Quinidine
Quinine
Ranitidine
Salicylic acid
Secobarbital
Serotonin (5-Hydroxytyramine)
Sulfamethazine
Sulindac
Temazepam
Tetracycline
Tetrahydrocortisone, 3-Acetate
Tetrahydrocortisone3 (β-D glucuronide)
Tetrahydrozoline
Thebaine
Thiamine
Thioridazine
Tolbutamine
Triamterene
Trifluoperazine
Trimethoprim
Trimipramine
D, L-Tryptophan
Tyramine
D, L-Tyrosine
Uric acid
Verapamil
Zomepirac

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Index of Symbols

IVD	For *in vitro* diagnostic use only	4 ~ 30 °C	Store between 4 ~ 30 °C
	Do not reuse		Manufacturer
	Keep away from sunlight		Keep dry