

mAMP

One Step

Methamphetamine Test Device

Package Insert

A rapid, one step test for the qualitative detection of Methamphetamines in human urine.

For healthcare professionals including professionals at point of care sites

For in vitro diagnostic use only.

INTENDED USE

The mAMP One Step Methamphetamine Test Device is a lateral flow chromatographic immunoassay for the detection of Methamphetamine in human urine.

This assay provides only a 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 an addictive stimulant drug that strongly activates certain systems in the brain. Methamphetamine is closely related chemically to amphetamine, but the central nervous system effects of Methamphetamine are greater. Methamphetamine is made in illegal laboratories and has a high potential for abuse and dependence. The drug can be taken orally, injected, or inhaled. Acute higher does lead to enhanced stimulation of the central nervous system and induce euphoria, alertness, reduced appetite, and a sense of increased energy and power. Cardiovascular responses to Methamphetamine include increased blood pressure and cardiac arrhythmias. More acute responses produce anxiety, paranoia, hallucinations, psychotic behavior, and eventually, depression and exhaustion.

The effects of Methamphetamine generally last 2-4 hours, and the drug has a half-life of 9-24 hours in the body. In urines of normal pH approximately 43% of a dose is eliminated as unchanged methamphetamine in a 24 hour period, with about 4-7% eliminated as amphetamine.³ Thus, the presence of the parent compound in the urine indicates Methamphetamine use. Methamphetamine is generally detectable in the urine for 3-5 days, depending on urine pH level.

The mAMP One Step Methamphetamine Test Device is a rapid urine screening test that can be performed without the use of an instrument. The test utilizes a monoclonal antibody to selectively detect elevated levels of Methamphetamine in urine. The mAMP One Step Methamphetamine Test Device yields a positive result when the Methamphetamine in urine exceeds 1,000 ng/mL.

PRINCIPLE

The mAMP One Step Methamphetamine Test Device is an immunoassay based on the principle of competitive binding. Drugs which may be present in the urine specimen compete against the drug conjugate for binding sites on the antibody. During testing, a urine specimen migrates upward by capillary action. Methamphetamine, if present in the urine specimen below 1,000 ng/mL, will not saturate the binding sites of antibody coated particles in the test device. The antibody coated particles will then be captured by immobilized Methamphetamine conjugate and a visible colored line will show up in the test line region. The colored line will

not form in the test line region if the Methamphetamine level exceeds 1,000 ng/mL because it will saturate all the binding sites of anti-Methamphetamine antibodies. A drug-positive urine specimen will not generate a colored line in the test line region because of drug competition, while a drug-negative urine specimen or a specimen containing a drug concentration less than the cut-off will generate a line in the test line region.

To serve as a procedural control, a colored line will always appear at the control line region, indicating that proper volume of specimen has been added and membrane wicking has occurred.

REAGENTS

The test device contains mouse monoclonal anti-Methamphetamine antibody-coupled particles and Methamphetamine-protein conjugate. A goat antibody is employed in the control line system.

PRECAUTIONS

- For healthcare professionals including professionals at point of care sites.
- For *in vitro* diagnostic use only. Do not use after the expiration date.
- The test device should remain in the sealed pouch until use.
- All specimens should be considered potentially hazardous and handled in the same manner as an infectious agent.
- The used test device should be discarded according to federal, state and local regulations.

STORAGE AND STABILITY

Store as packaged in the sealed pouch at 2-30°C. The test device is stable through the expiration date printed on the sealed pouch. The test device must remain in the sealed pouch until use. **DO NOT FREEZE.** Do not use beyond the expiration date.

SPECIMEN COLLECTION AND PREPARATION

Urine Assay

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

Specimen Storage

Urine specimens may be stored at 2-8°C for up to 48 hours prior to assay. For prolonged storage, specimens may be frozen and stored below -20°C. Frozen specimens should be thawed and mixed before testing.

MATERIALS

Materials Provided

- Test devices
- Disposable specimen droppers
- Package insert

Materials Required But Not Provided

- Specimen collection container
- Timer
- External controls

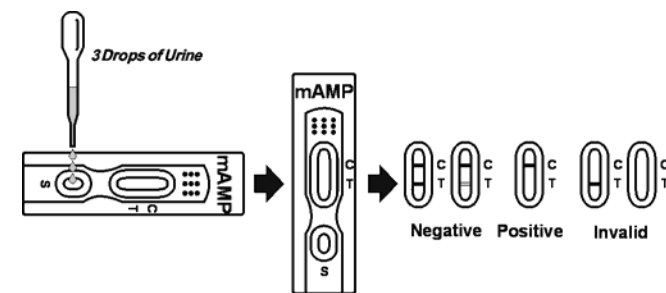
DIRECTIONS FOR USE

Allow test device, urine specimen, and/or controls to reach room temperature (15-30°C) prior to testing.

1. Bring the pouch to room temperature before opening it. Remove the test device from the sealed pouch and use it as soon as possible.
2. Place the test device on a clean and level surface. Hold the dropper vertically and transfer 3 full drops of urine (approx. 100µl) to the specimen well (S) of the

test device, and then start the timer. Avoid trapping air bubbles in the specimen well (S). See the illustration below.

3. Wait for the red line(s) to appear. The result should be read at 5 minutes. Do not interpret the result after 10 minutes.



INTERPRETATION OF RESULTS

(Please refer to the illustration above)

NEGATIVE:* **Two lines appear.** One red line should be in the control region (C), and another apparent red or pink line should be in the test region (T). This negative result indicates that the Methamphetamine concentration is below the detectable level (1,000 ng/mL).

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

POSITIVE: One red line appears in the control region (C). No line appears in the test region (T). This positive result indicates that the Methamphetamine concentration exceeds the detectable level (1,000 ng/mL).

INVALID: Control line fails to appear. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test using a new test device. If the problem persists, discontinue using the lot immediately and contact your local distributor.

QUALITY CONTROL

A procedural control is included in the test. A red line appearing in the control region (C) is considered an internal positive 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.

LIMITATION

1. The mAMP One Step Methamphetamine Test Device 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) are the preferred confirmatory methods.^{1,2}
2. It is possible that technical or procedural errors, as well as other interfering substances in the urine specimen may cause erroneous results.
3. Adulterants, such as bleach and/or alum, in urine specimens may produce erroneous results regardless of the analytical method used. If adulteration is suspected, the test should be repeated with another urine specimen.
4. A Positive Result does not indicate level or intoxication, administration route or concentration in urine.
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.

PERFORMANCE CHARACTERISTICS

Accuracy

A side-by-side comparison was conducted using the mAMP One Step Methamphetamine Test Device and a leading commercially available mAMP rapid test. Testing was performed on 300 clinical specimens. Ten percent of the specimens employed were either at -25% or +25% level of the cut-off concentration of 1,000 ng/mL Methamphetamine. Presumptive positive results were confirmed by GC/MS. The following results were tabulated:

Method		Other mAMP Rapid Test		Total Results
mAMP One Step Test Device	Results	Positive	Negative	
	Positive	147	0	147
	Negative	1	152	153
Total Results		148	152	300
% Agreement with this commercial kit		99%	100%	99%

When compared at 1,000 ng/mL cut-off with GC/MS, the following results were tabulated:

Method		GC/MS		Total Results
mAMP One Step Test Device	Results	Positive	Negative	
	Positive	135	12	147
	Negative	1	152	153
Total Results		136	164	300
% Agreement with GC/MS Analysis		99%	93%	96%

Eighty (80) of these samples were also run using the mAMP One Step Methamphetamine Test Device by an untrained operator at a different site. Based on GC/MS data, the operator obtained a statistically similar Positive Agreement, Negative Agreement and Overall Agreement rate as the laboratory personnel.

Analytical Sensitivity

A drug-free urine pool was spiked with Methamphetamine at the following concentrations: 0 ng/mL, 500 ng/mL, 750 ng/mL, 1,000 ng/mL, 1,250 ng/mL and 1,500 ng/mL. The result demonstrates >99% accuracy at 50% above and 50% below the cut-off concentration. The data are summarized below:

Methamphetamine Concentration (ng/mL)	Percent of Cutoff	n	Visual Result	
			Negative	Positive
0	0%	30	30	0
500	-50%	30	30	0
750	-25%	30	24	6
1,000	Cutoff	30	18	12
1,250	+25%	30	1	29
1,500	+50%	30	0	30

Analytical Specificity

The following table lists compounds that are positively detected in urine by the mAMP One Step Methamphetamine Test Device at 5 minutes.

Compound	Concentration (ng/mL)
p-Hydroxymethamphetamine	30,000
D-Methamphetamine	1,000
L-Methamphetamine	8,000
(±)-3,4-Methylenedioxymethamphetamine	2,000
Mephentermine	50,000

Precision

A study was conducted at 3 physician's offices by untrained operators using 3 different lots of product to demonstrate the within run, between run and between operator precision. An identical panel of coded specimens containing no

Methamphetamine, 25% Methamphetamine above and below the cut-off and 50% Methamphetamine above and below the 1,000 ng/mL cut-off was provided to each site. The results are given below:

Methamphetamine concentration (ng/mL)	n	Site A		Site B		Site C	
		-	+	-	+	-	+
0	15	15	0	15	0	15	0
500	15	15	0	15	0	14	1
750	15	10	5	2	13	13	2
1,250	15	0	15	0	15	1	14
1,500	15	0	15	0	15	0	15

Effect of Urinary Specific Gravity

Fifteen (15) urine samples of normal, high, and low specific gravity ranges were spiked with 500 ng/mL and 1,500 ng/mL of Methamphetamine respectively. The mAMP One Step Methamphetamine Test Device was tested in duplicate using the fifteen neat and spiked urine samples. The results demonstrate that varying ranges of urinary specific gravity does not affect the test results.

Effect of the Urinary pH

The pH of an aliquoted negative urine pool was adjusted to a pH range of 5 to 9 in 1 pH unit increments and spiked with Methamphetamine to 500 ng/mL and 1,500 ng/mL. The spiked, pH-adjusted urine was tested with the mAMP One Step Methamphetamine Test Device in duplicate. The results demonstrate that varying ranges of pH does not interfere with the performance of the test.

Cross-Reactivity

A study was conducted to determine the cross-reactivity of the test with compounds in either drug-free urine or Methamphetamine positive urine. The following compounds show no cross-reactivity when tested with the mAMP One Step Methamphetamine Test Device at a concentration of 100 µg/mL.

Non Cross-Reacting Compounds

4-Acetamidophenol	Erythromycin	Papaverine
Acetophenetidin	β-Estradiol	Penicillin-G
N-Acetylprocainamide	Estrone-3-sulfate	Pentobarbital
Acetylsalicylic acid	Ethyl-p-aminobenzoate	Perphenazine
Aminopyrine	Fenfluramine	Phencyclidine
Amitypyline	Fenopifen	Phenelzine
Amobarbital	Furosemide	Phenobarbital
Amoxicillin	Gentisic acid	Phentermine
Ampicillin	Hemoglobin	L-Phenylephrine
Ascorbic acid	Hydralazine	β-Phenylethylamine
D-Amphetamine	Hydrochlorothiazide	Phenylpropanolamine
D,L-Amphetamine	Hydrocodone	Prednisolone
L-Amphetamine	Hydrocortisone	Prednisone
Apomorphine	p-Hydroxyamphetamine	Procaine
Aspartame	O-Hydroxyhippuric acid	Promazine
Atropine	3-Hydroxytyramine	Promethazine
Benzilic acid	Ibuprofen	D,L-Propranolol
Benzoic acid	Imipramine	D-Propoxyphene
Benzoylcegonine	Iproniazid	D-Pseudoephedrine
Benzphetamine	(-) Isoproterenol	Quinacrine
Bilirubin	Isoxsuprine	Quinidine
Brompheniramine	Ketamine	Quinine
Caffeine	Ketoprofen	Ranitidine
Cannabidiol	Labetalol	Salicylic acid

Chloralhydrate	Levorphanol	Secobarbital
Chloramphenicol	Loperamide	Serotonin (5-Hydroxytyramine)
Chlordiazepoxide	Maprotiline	Sulfamethazine
Chlorothiazide	Meperidine	Sulindac
(±) Chlorpheniramine	Meprobamate	Temazepam
Chlorpromazine	Methadone	Tetrazepam
Chlorquine	Methoxyphenamine	Tetracycline
Cholesterol	(+) 3,4-Methylenedioxyamphetamine	Tetrahydrocortisone, 3
Clomipramine	3,4-Methylenedioxyethylamphetamine	Acetate
Clonidine	Methylphenidate	Tetrahydrocortisone 3 (β-D-glucuronide)
Cocaethylene	Morphine-3-β-D-glucuronide	Tetrahydrozoline
Cocaine hydrochloride	Nalidixic acid	Thiamine
Codeine	Naloxone	Thioridazine
Cortisone	Naltrexone	D, L-Tyrosine
(-) Cotinine	Naproxen	Tolbutamine
Creatinine	Niacinamide	Trans-2-phenylcyclopropylamine
Deoxycorticosterone	Nifedipine	Triamterene
Dextromethorphan	Norethindrone	Trifluoperazine
Diazepam	D-Norpropoxyphene	Trimethoprim
Diclofenac	Noscapine	Trimipramine
Diflunisal	D,L-Octopamine	Tryptamine
Digoxin	Oxalic acid	D, L-Tryptophan
Diphenhydramine	Oxazepam	Tyramine
Doxylamine	Oxolinic acid	Uric acid
Egonine hydrochloride	Oxycodone	Verapamil
Egonine methylester (1R,2S)-(-)-Ephedrine	Oxymetazoline	Zomepirac
L-Epinephrine		
(-) Y Ephedrine		

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