

SureStep™ MET Methamphetamine Test Device (Urine) Package Insert

English

A rapid, one step test for the qualitative detection of Methamphetamine in human urine. For medical and other professional *in vitro* diagnostic use only.

INTENDED USE

The MET One Step Methamphetamine Test Device (Urine) is a lateral flow chromatographic immunoassay for the detection of Methamphetamine in human urine at a cut-off concentration of 1,000 ng/mL. This test will detect other related compounds, please refer to the Analytical Specificity table in this package insert.

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 and 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 doses 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. Methamphetamine is excreted in the urine primarily as Amphetamine, and oxidized and deaminated derivatives. However, 10-20% of Methamphetamine is excreted unchanged. 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 MET One Step Methamphetamine Test Device (Urine) 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 MET One Step Methamphetamine Test Device (Urine) yields a positive result when the Methamphetamine in urine exceeds 1,000 ng/mL.

PRINCIPLE

The MET One Step Methamphetamine Test Device (Urine) 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. 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 contains mouse monoclonal anti-Methamphetamine antibody-coupled particles and Methamphetamine-protein conjugate. A goat antibody is employed in the control line system.

PRECAUTIONS

- For medical and other professional *in vitro* diagnostic use only. Do not use after the expiration date.
- The test 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 should be discarded according to local regulations.

STORAGE AND STABILITY

Store as packaged in the sealed pouch either at room temperature or refrigerated (2-30°C). The test is stable through the expiration date printed on the sealed pouch. The test 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 to settle to obtain a clear supernatant 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

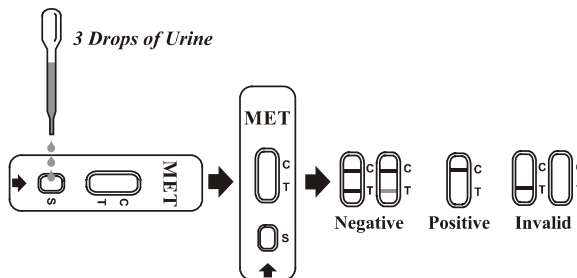
Materials Provided

- Test devices
- Dropers
- Package insert
- Materials Required But Not Provided
- Timer

DIRECTIONS FOR USE

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

- Bring the pouch to room temperature before opening it. Remove the test device from the sealed pouch and use it as soon as possible.
- Place the test device on a clean and level surface. Hold the dropper vertically and transfer 3 full drops of urine (approx. 100 µL) 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.
- Wait for the colored line(s) to appear. Read results at 5 minutes. It is important that the background is clear before the result is read. Do not interpret the result after 10 minutes.



INTERPRETATION OF RESULTS

(Please refer to the illustration above)

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

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

POSITIVE: One colored line appears in the control line region (C). No line appears in the test line 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. 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 colored line appearing in the control line 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

- The MET One Step Methamphetamine Test Device (Urine) 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.^{1,2}
- It is possible that technical or procedural errors, as well as other interfering substances in the urine specimen may cause erroneous results.
- 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.
- A positive result indicates presence of the drug or its metabolites but does not indicate level of intoxication, administration route or concentration in urine.
- A negative result may not necessarily indicate drug-free urine. Negative results can be obtained when drug is present but below the cut-off level of the test.
- Test does not distinguish between drugs of abuse and certain medications.

PERFORMANCE CHARACTERISTICS

Accuracy

A side-by-side comparison was conducted using the MET One Step Methamphetamine Test Device (Urine) and a leading commercially available MET rapid test. Testing was performed on 300 clinical specimens previously collected from subjects present for Drug Screen Testing. 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 MET Rapid Test		Total Results
	Positive	Negative	
MET One Step Test Device	147	0	147
	1	152	153
Total Results	148	152	300
% Agreement	99%	>99%	99%

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

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

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 Cut-off	n	Visual Result	
			Negative	Positive
0	0	30	30	0
500	-50%	30	30	0
750	-25%	30	24	6
1,000	Cut-off	30	1	29
1,250	+25%	30	0	30
1,500	+50%	30	0	30

Analytical Specificity

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

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

Precision

A study was conducted at three physicians' offices by untrained operators using three different lots of product to demonstrate the within run, between run and between operator precision. An identical panel of coded specimens containing, according to GC/MS, 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.

Methamphetamine Concentration (ng/mL)	n per site	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 urine specimens of normal, high, and low specific gravity ranges were spiked with 500 ng/mL and 1,500 ng/mL of Methamphetamine. The MET One Step Methamphetamine Test Device (Urine) was tested in duplicate using the fifteen neat and spiked urine specimens. The results demonstrate that varying ranges of urinary specific gravity do not affect the test results.

Effect of 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 MET One Step Methamphetamine Test Device (Urine) in duplicate. The results demonstrate that varying ranges of pH do 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 MET One Step Methamphetamine Test Device (Urine) at a concentration of 100 µg/mL.

Non Cross-Reacting Compounds

4-Acetamidophenol	Creatinine	Loperamide	Prednisone
Acetophenetidin	Deoxycorticosterone	Maprotiline	Procaine
N-Acetylprocainamide	Dextromethorphan	Meperidine	Promazine
Acetylsalicylic acid	Diazepam	Meprobamate	Propofolone
Aminopyrine	Diclofenac	Methadone	D,L-Propranolol
Amitypyline	Diflunisal	Methoxyphenamine	D-Propoxyphene
Amobarbital	Digoxin	(+)-3,4-Methylenedioxyamphetamine	D-Pseudoephedrine
Amoxicillin	Diphenhydramine	amphetamine	Quinacrine
Ampicillin	Doxylamine	3,4-Methylenedioxyethylamphetamine	Quinidine
L-Ascorbic acid	Egonine hydrochloride	amphetamine	Quinine
D-Amphetamine	Egonine methyl ester	Morphinephenadate	Ranitidine
D,L-Amphetamine	(1R,2S)-(-)-Ephedrine	Morphine-3-β-D-glucuronide	Salicylic acid
L-Amphetamine	L-Ephedrine	glucuronide	Secobarbital
Apomorphine	(-)-ψ-Ephedrine	Nalidixic acid	Serotonin
Aspartame	Erythromycin	Naloxone	(5-Hydroxytryptamine)
Atropine	β-Estradiol	Naltrexone	Sulfamethazine
Benzoic acid	Estrone-3-sulfate	Naproxen	Sulindac
Benzoic acid	Ethyl-p-aminobenzoate	Niacinamide	Temazepam
Benzoylegonine	Fenfluramine	Nifedipine	Tetracycline
Benzphetamine	Fenpropion	Norethindrone	Tetrahydrocortisone
Bilirubin	Furosemide	D-Norpropoxyphene	3-Acetate
(±)-Brompheniramine	Genisteic acid	Noscapine	Tetrahydrocortisone
Caffeine	Hemoglobin	D,L-Octopamine	3-β-D glucuronide)
Cannabidiol	Hyalazaline	Oxalic acid	Tetrahydrozoline
Chloralhydrate	Hydrochlorothiazide	Oxazepam	Thiamine
Chloramphenicol	Hydrocodone	Oxalic acid	Thioridazine
Chloridazepoxide	Hydrocortisone	Oxycodone	D, L-Tyrosine
Chloridiazepoxide	p-Hydroxyamphetamine	Oxymetazoline	Tolbutamide
(±) Chlorpheniramine	O-Hydroxyhippuric acid	Papaverine	Trans-2-phenyl cyclopropylamine
Chlorpromazine	3-Hydroxytyramine	Penicillin-G	Triamterene
Chlorquine	Ibuprofen	Pentobarbital	Trifluoperazine
Cholesterol	Imipramine	Perphenazine	Trimethoprim
Clomipramine	Iproniazid	Phencyclidine	Trimipramine
Clonidine	(±)-Isoproterenol	Phenelzine	Tryptamine
Coacetylene	Isoxsuprine	Phenobarbital	D, L-Tryptophan
Cocaine hydrochloride	Ketamine	Phentermine	Tyramine
Codine	Ketoprofen	L-Phenylephrine	Uric acid
Cortisone	Labetalol	β-Phenylethylamine	Verapamil
(-) Cotinine	Levorphanol	Phenylpropanolamine	Zomepirac
		Prednisolone	

BIBLIOGRAPHY

- Baselt RC. Disposition of Toxic Drugs and Chemicals in Man, 2nd Ed. Biomedical Publ., Davis, CA. 1982; 488
- Hawks RL, CN Chiang. Urine Testing for Drugs of Abuse. National Institute for Drug Abuse (NIDA), Research Monograph 73, 1986

Index of Symbols

	Attention, see instructions for use		Tests per kit		Authorized Representative
	For <i>in vitro</i> diagnostic use only		Use by		Do not reuse
	Store between 2-30°C		Lot Number		Catalog #



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Number: 1155835401
Effective date: 2006-xx-xx