



MET Rapid Test Cassette (Urine)

Package Insert

REF DME-102 English

A rapid test for the qualitative detection of Methamphetamine in human urine. For professional *in vitro* diagnostic use only.

INTENDED USE

The MET Rapid Test Cassette is a rapid chromatographic immunoassay for the detection of Methamphetamine in human urine at the cut-off concentration of 1,000 ng/mL. This test will detect other compounds, please refer to Analytical Specificity table in this package insert.

This assay provides only a qualitative, preliminary 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 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 have 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 Rapid Test Cassette 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 Rapid Test Cassette yields a positive result when the Methamphetamine in urine exceeds 1,000 ng/mL.

PRINCIPLE

The MET Rapid Test Cassette 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 the 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 is at or above 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 particles should be centrifuged, filtered, or allowed to settle to obtain clear specimen for testing.

Specimen Storage

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

MATERIALS

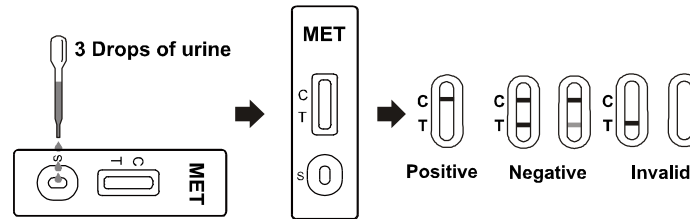
Materials Provided

- Test cassettes
- Droppers
- Package insert
- Materials Required But Not Provided
- Specimen collection containers
- Timer

DIRECTIONS FOR USE

Allow the 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 cassette from the sealed pouch and use it within one hour.
- Place the test cassette on a clean and level surface. Hold the dropper vertically and transfer **3 full drops of urine** (approx. 120 µL) to the specimen well (S) of the test cassette, 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. **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 colored lines appear. One colored line should be in the control region (C) and another colored line should be in the test region (T). This negative result indicates that the Methamphetamine concentration is below the detectable level of 1,000 ng/mL.

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

POSITIVE: One colored line appears in the control region (C). No line appears in the test region (T). This positive result indicates that the Methamphetamine concentration is above the detectable level of 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 with a new test cassette. If the problem persists, discontinue using the test cassette immediately and contact your local distributor.

QUALITY CONTROL

A procedural control is included in the test. A colored line appearing in the control region (C) is considered an internal procedural control. It confirms sufficient specimen volume 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 testing practices to confirm the test procedure and to verify proper test performance.

LIMITATIONS

- The MET Rapid Test Cassette provides only a qualitative, preliminary result. A secondary analytical method must be used to obtain a confirmed result. Gas chromatography/mass spectrophotometry (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 Rapid Test Cassette and a commercially available MET rapid test. Testing was performed on 107 clinical specimens previously collected from subjects present for Drug Screen Testing. The following results were tabulated:

Method	Other MET Rapid Test			Total Results
	Results	Positive	Negative	
	MET Rapid Test cassette	Positive	55	
	Negative	0	52	52
Total Results		55	52	107
% Agreement		>99.9%	>99.9%	>99.9%

A side-by-side comparison was conducted using the MET Rapid Test Cassette and GC/MS at the cut-off of 1,000 ng/mL. Testing was performed on 250 clinical specimens previously collected from subjects present for Drug Screen Testing. The following results were tabulated:

Method	GC/MS		Total Results	
	Results	Positive		Negative
	MET Rapid Test Cassette	Positive		76

	Negative	3	166	169
Total Results	79	171	250	
% Agreement	96.2%	97.1%	96.8%	

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, 1,500 ng/mL and 3,000 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	27	3
1,000	Cut-off	30	16	14
1,250	+25%	30	3	27
1,500	+50%	30	0	30
3,000	3X	30	0	30

Analytical Specificity

The following table lists compounds that are positively detected in urine by the MET Rapid Test Cassette at 5 minutes.

Compound	Concentration (ng/mL)
ρ-Hydroxymethamphetamine	25,000
D-Methamphetamine	1,000
L-Methamphetamine	20,000
(±)-3,4-Methylenedioxymethamphetamine	12,500
Mephentermine	50,000

Precision

A study was conducted at three hospitals 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	10	10	0	10	0	10	0
500	10	10	0	10	0	10	0
750	10	9	1	9	1	9	1
1,250	10	1	9	2	8	1	9
1,500	10	0	10	0	10	0	10

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 Rapid Test Cassette 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 Rapid Test Cassette 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 Rapid Test Cassette 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	Promethazine
Aminopyrine	Diclofenac	Methadone	D,L-Propranolol
Amitypyline	Diffunisal	Methoxyphenamine	D-Propoxyphene
Amobarbital	Digoxin	(+) 3,4-Methylenedioxy-amphetamine	D-Pseudoephedrine
Amoxicillin	Diphenhydramine	Ampicillin	Quinacrine
Ampicillin	Doxylamine	3,4-Methylenedioxyethyl-	Quinidine
L-Ascorbic acid	Ecgonine hydrochloride	amphetamine	Quinine
D-Amphetamine	Ecgonine methylester	Methylphenidate	Ranitidine
D,L-Amphetamine	(1R,2S)-(-)-Ephedrine	Morphine-3-β-D-glucuronide	Salicylic acid
L-Amphetamine	L-Epinephrine	glucuronide	Secobarbital
Apomorphine	(-)-ψ-Ephedrine	Nalidixic acid	Serotonin
Aspartame	Erythromycin	Naloxone	(5-Hydroxytryptamine)
Atropine	β-Estradiol	Naltrexone	Sulfamethazine

Benzilic acid	Estrone-3-sulfate	Naproxen	Sulindac
Benzoic acid	Ethyl-p-aminobenzoate	Niacinamide	Temazepam
Benzoylcegonine	Fenfluramine	Nifedipine	Tetracycline
Benzphetamine	Fenoprofen	Norethindrone	Tetrahydrocortisone
Bilirubin	Furosemide	D-Norpropoxyphene	3-Acetate
(±)-Brompheniramine	Gentisic acid	Noscapine	Tetrahydrocortisone
Caffeine	Hemoglobin	D,L-Octopamine	3-(β-D glucuronide)
Cannabidiol	Hydralazine	Oxalic acid	Tetrahydrozoline
Chloralhydrate	Hydrochlorothiazide	Oxazepam	Thiamine
Chloramphenicol	Hydrocodone	Oxolinic acid	Thioridazine
Chlordiazepoxide	Hydrocortisone	Oxycodone	D, L-Tyrosine
Chlorothiazide	p-Hydroxyamphetamine	Oxymetazoline	Tolbutamine
(±) 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
Coccaethylene	Isoxsuprine	Phenobarbital	D, L-Tryptophan
Cocaine hydrochloride	Ketamine	Phentermine	Tyramine
Codeine	Ketoprofen	L-Phenylephrine	Uric acid
Cortisone	Labetalol	β-Phenylethylamine	Verapamil
(-) Cotinine	Levorphanol	Phenylpropanolamine	Zomepirac
		Prednisolone	

【BIBLIOGRAPHY】

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

Index of Symbols

	Consult instructions for use or consult electronic instructions for use		Contains sufficient for <n> tests		Temperature limit
	<i>In vitro</i> diagnostic medical device		Batch code		Catalogue number
	Authorized representative in the European Community/European Union		Use-by date		Do not re-use
	Do not use if package is damaged and consult instructions for use		Manufacturer		Caution

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