MET Rapid Test Cassette (Urine)
Package Insert

REF DME-102
English

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

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 1000ng/ml. This test will detect other compounds, please refer to Analytical Specificity table in this package insert.

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 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 1,000ng/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 1000ng/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 1000ng/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

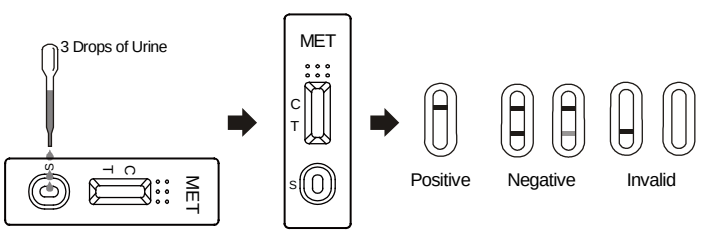
Materials Required But Not Provided

- Specimen collection containers
- Timer

DIRECTIONS FOR USE

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

1. Bring the pouch to room temperature before opening it. Remove the test cassette from the sealed pouch and use it within one hour.
2. 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.
3. Wait for the color 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 colored line should be in the control region (C), and another apparent colored line should be in the test region (T). This negative result indicates that the Methamphetamine concentration is below the detectable level of 1000ng/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 1000ng/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 color 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 test cassette; 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

1. The MET Rapid Test Cassette provides only a qualitative, preliminary analytical result. A secondary analytical method must be used to obtain a confirmed result. Gas chromatography/mass spectrophotometry (GC/MS) is the preferred confirmatory method1.2.
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 indicates presence of the drug or its metabolites but does not indicate level of 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 cut-off level of the test.
6. Test does not distinguish between drugs of abuse and certain medications.

EXPECTED VALUES

This negative result indicates that the Methamphetamine concentration is below the detectable level of 1000ng/ml. Positive result means the concentration of Methamphetamine is above the level of 1000ng/ml. The MET Rapid Test Cassette has a sensitivity of 1000ng/ml.

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
The MET Rapid Test cassette	Results	Positive	Negative	
	Positive	55	0	55
	Negative	0	52	52
Total Results		55	52	107
% Agreement with this Rapid Test		>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 1000ng/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
The MET Rapid Test Cassette	Results	Positive	Negative	
	Positive	76	5	81
	Negative	3	166	169
Total Results		79	171	250
% Agreement with this Rapid Test		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	26	4
1,000	Cut-off	30	14	16
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 by laypersons 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.

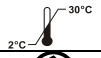
Non Cross-Reacting Compounds

4-Acetamidophenol	Creatinine	Loperamide	Prednisone
Acetophenetidin	Deoxycorticosterone	Maprotiline	Procaine
N-Acetylprocainamide	Dextromethorphan	Meperidine	Promazine
Acetylsalicylic acid	Diazepam	Meprobamate	Promethazine
Aminopyrine	Diclofenac	Methadone	D,L-Propanolol

Amitryptyline	Diflunisal	Methoxyphenamine	D-Propoxyphene
Amobarbital	Digoxin	(+) 3,4-Methylenedioxy-	D-Pseudoephedrine
Amoxicillin	Diphenhydramine	amphetamine	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-	Salicylic acid
L-Amphetamine	L-Epinephrine	glucuronide	Secobarbital
Apomorphine	(-)-ψ-Ephedrine	Nalidixic acid	Serotonin
Aspartame	Erythromycin	Naloxone	(5-Hydroxytyramine)
Atropine	β-Estradiol	Naltrexone	Sulfamethazine
Benzilic acid	Estrone-3-sulfate	Naproxen	Sulindac
Benzoic acid	Ethyl-p-aminobenzoate	Niacinamide	Temazepam
Benzoylecgonine	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
Chlorpromazine	3-Hydroxytyramine	Penicillin-G	cyclopropylamine
Chlorquine	Ibuprofen	Pentobarbital	Triamterene
Cholesterol	Imipramine	Perphenazine	Trifluoperazine
Clomipramine	Iproniazid	Phencyclidine	Trimethoprim
Clonidine	(±)-Isoproterenol	Phenelzine	Trimipramine
Cocaethylene	Isoxsuprine	Phenobarbital	Tryptamine
Cocaine hydrochloride	Ketamine	Phentermine	D, L-Tryptophan
Codeine	Ketoprofen	L-Phenylephrine	Tyramine
Cortisone	Labetalol	β-Phenylethylamine	Uric acid
(-) Cotinine	Levorphanol	Phenylpropanolamine	Verapamil
Prednisolone	Zomepirac		

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

	Attention, see instructions for use
	For in vitro diagnostic use only
	Store between 2-30°C
	Do not use if package is damaged
	Authorized Representative
	Catalog #
	Tests per kit
	Use by
	Lot Number
	Manufacturer
	Do not reuse
	Consult Instructions for Use

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