

# MET Rapid Test Dipstick (Urine)

## Package Insert

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 Dipstick is a rapid chromatographic immunoassay for the detection of Methamphetamine in human urine at the cut-off concentration of 300ng/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 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 Rapid Test Dipstick 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 Dipstick yields a positive result when the Methamphetamine in urine exceeds 300ng/mL.

### PRINCIPLE

The MET Rapid Test Dipstick 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 300ng/mL, will not saturate the binding sites of the 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 is at or above 300ng/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 at room temperature or refrigerated (2-30°C). The test is stable through the expiration date printed on the sealed pouch or label of the closed canister. The test must remain in the sealed pouch or closed canister until use. **DO NOT FREEZE.** Do not use beyond the expiration date.

NOTE: Once the canister has been opened, the remaining test(s) are stable for 50 days only.

### 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 testing. For long-term storage, specimens may be frozen and stored below -20°C. Frozen specimens should be thawed and mixed before testing.

### MATERIALS

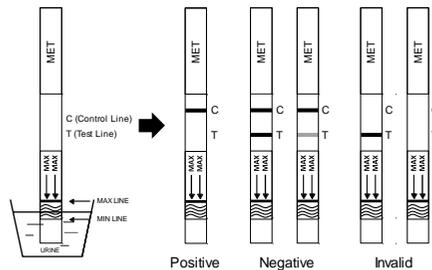
#### Materials Provided

- Test Dipsticks
- Package insert
- Materials Required But Not Provided
- 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 Dipstick from the sealed pouch and use it within one hour.
- With arrows pointing toward the urine specimen, immerse the Test Dipstick vertically in the urine specimen for at least 10-15 seconds. Do not pass the maximum line (MAX) on the Test Dipstick when immersing the strip. See the illustration below.
- Place the Test Dipstick on a non-absorbent flat surface, start the timer and wait for the colored line(s) to appear. **Read results 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 color line should be in the control region ©, and another apparent color line should be in the test region (T). This negative result indicates that the Methamphetamine concentration is below the detectable level of 300ng/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 color line appears in the control region ©. No line appears in the test region (T). This positive result indicates that the Methamphetamine concentration is above the detectable level of 300ng/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 Dipstick. If the problem persists, discontinue using the Test Dipstick immediately and contact your local distributor.

### QUALITY CONTROL

A procedural control is included in the test. A color line appearing in the control region © is considered an internal procedural control. It confirms sufficient specimen volume and correct procedural technique.

Control standards are not supplied with this Test Dipstick; 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 Dipstick provides only a qualitative, preliminary analytical result. A secondary analytical method must be used to obtain a confirmed result.<sup>1,2</sup> Gas chromatography/mass spectrophotometry (GC/MS) is the preferred confirmatory method.
- 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.

### EXPECTED VALUES

This negative result indicates that the Methamphetamine concentration is below the detectable level of 300ng/mL. Positive result means the concentration of Methamphetamine is above the level of 300ng/mL. The MET Rapid Test Dipstick has a sensitivity of 300ng/mL.

### PERFORMANCE CHARACTERISTICS

#### Accuracy

A side-by-side comparison was conducted using The MET Rapid Test Dipstick 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
	Positive	Negative	
The MET Rapid Test Dipstick	Positive	0	57
	Negative	50	50
	Total Results	57	50
% Agreement with this Rapid Test		>99.9%	>99.9%

A side-by-side comparison was conducted using The MET Rapid Test and GC/MS at the cut-off of 300ng/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
	Positive	Negative	
The MET Rapid Test Dipstick	Positive	4	92
	Negative	156	158
	Total Results	90	160
% Agreement with this Rapid Test		97.8%	97.5%

#### Analytical Sensitivity

A drug-free urine pool was spiked with Methamphetamine at the following concentrations: 0 ng/mL, 150 ng/mL, 225 ng/mL, 300 ng/mL, 375ng/mL 450 ng/mL and 900 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
150	-50%	30	30	0
225	-25%	30	27	3
300	Cut-off	30	16	14
375	+25%	30	3	27
450	+50%	30	0	30
900	3X	30	0	30

### Analytical Specificity

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

Compound	Concentration (ng/mL)
p-Hydroxymethamphetamine	7,500
D-Methamphetamine	300
L-Methamphetamine	6,000
(±)-3,4-Methylenedioxyamphetamine	3,750
Mephentermine	15,000

### Precision

A study was conducted at three physicians' offices 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 300 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
150	10	10	0	10	0	10	0
225	10	9	1	9	1	9	1
375	10	1	9	1	9	1	9
450	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 150 ng/mL and 450 ng/mL of Methamphetamine. The MET Rapid Test Dipstick 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 150 ng/mL and 450 ng/mL. The spiked, pH-adjusted urine was tested with The MET Rapid Test Dipstick 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 Dipstick at a concentration of 100 µg/mL.

### Non Cross-Reacting Compounds

4-Acetamidophenol	Creatinine	Loperamide	Prednisone
Acetophenetidin	Deoxycorticosterone	Maprotiline	Procaine
N-Acetylprocainamide	Dextromethorphan	Mepredine	Promazine
Acetylsalicylic acid	Diazepam	Meprobamate	Promethazine
Aminopyrine	Diufenac	Metadone	D,L-Propranolol
Amitriptyline	Diflunisal	Methoxyphenamine	D-Pseudoephedrine
Amobarbital	Digoxin	(+) 3,4-Methylenedioxyamphetamine	Quinacrine
Amoxicillin	Diphenhydramine	Doxylamine	Quinidine
Ampicillin	Ecgonine hydrochloride	Ecgonine methylester	Quinine
L-Ascorbic acid	D-Amphetamine	(1R,2S)-(-)-Ephedrine	Ramitidine
D-Amphetamine	D,L-Amphetamine	L-Epinephrine	Salicylic acid
D,L-Amphetamine	L-Amphetamine	(-)-ψ-Ephedrine	Secobarbital
L-Amphetamine	Apomorphine	Erythromycin	Serotonin
Apomorphine	Aspartame	β-Estradiol	(5-Hydroxytryptamine)
Aspartame	Atropine	Estrone-3-sulfate	Sulfamethazine
Atropine	Benzilic acid	Benzoic acid	Sulindac
Benzilic acid	Benzoic acid	Benzoylecgonine	Temazepam
Benzoic acid	Benzoylecgonine	Benzphetamine	Tetracycline
Benzoylecgonine	Benzphetamine	Bilirubin	Tetrahydrocortisone
Benzphetamine	Bilirubin	(±)-Brompheniramine	Tetrahydrocortisone
Bilirubin	(±)-Brompheniramine	Caffeine	3-(β-D glucuronide)
(±)-Brompheniramine	Caffeine	Cannabidiol	Tetrahydrozoline
Caffeine	Cannabidiol	Chloralhydrate	Thiamine
Cannabidiol	Chloralhydrate	Chloramphenicol	Thioridazine
Chloralhydrate	Chloramphenicol	Chloridiazepoxide	Oxycodone
Chloramphenicol	Chloridiazepoxide	Chlorothiazide	Oxymetazoline
Chloridiazepoxide	Chlorothiazide	(±) Chlorpheniramine	Papaverine
Chlorothiazide	(±) Chlorpheniramine	Chlorpromazine	O-Hydroxyhippuric acid
(±) Chlorpheniramine	Chlorpromazine	Chlorzoxiprone	3-Hydroxytyramine
Chlorpromazine	Chlorzoxiprone	Cholesterol	Ibuprofen
Chlorzoxiprone	Cholesterol	Clomipramine	Imipramine
Cholesterol	Clomipramine	Clonidine	Iproniazid
Clomipramine	Clonidine	Cocaine	(±)-Isoproterenol
Clonidine	Cocaine	Cocaine hydrochloride	Phenobarbital
Cocaine	Cocaine hydrochloride	Cocaine	Phentermine
Cocaine hydrochloride	Cocaine	Codine	L-Phenylephrine
Codine	Codine	Cortisone	Phenylephrine
Cortisone	Cortisone	(-) Cotinine	Phenylpropanolamine
(-) Cotinine	(-) Cotinine		Prednisolone

### BIBLIOGRAPHY

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

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