

INSTANT-VIEW[®] Methamphetamine (1000) Urine Dip-Strip Test

One Step Assay
Rapid Visual Results
For Qualitative In Vitro Diagnostic Use

INTENDED USE

This device is a qualitative immunoassay intended to provide qualitative screening results for methamphetamine in human urine at a cutoff concentration of 1000ng/ml. It is for health care professional use only.

This assay provides only a preliminary 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 obtained.

SUMMARY AND EXPLANATION OF THE TEST

Methamphetamine in overdose causes restlessness, confusion, anxiety, hallucinations, cardiac arrhythmias, hypertension, hyperthermia, circulatory collapse, convulsions, and coma. Methamphetamine has been implicated in fatal poisonings following both intravenous and oral administration. Chronic abusers may develop paranoid psychosis. D-Methamphetamine (d-desoxyephedrine, Desoxyn, Methedrine) is the N-methyl derivative of amphetamine. It is utilized in the treatment of obesity. Methamphetamine is administered by oral, nasal insufflation, or intravenous injection with duration of 2-4 hours. Methamphetamine undergoes some N-demethylation to amphetamine, its major active metabolite. During normal conditions up to 43% of a dose is eliminated unchanged in the 24-hour urine, with about 4-7% as amphetamine. In acid urine, up to 76% is found as unchanged drug and 7% as amphetamine in 24 hours, whereas in alkaline urine the corresponding values are 2% and less than 0.1%. Methamphetamine urine concentrations of 0.5-4.0 mg/L are commonly observed during the first 24 hours after ingestion of 10 mg. Methamphetamine concentrations of 24-333 mg/L (average, 142) were observed in the urine of methamphetamine abusers.

PRINCIPLE OF THE PROCEDURE

This assay is a one-step lateral flow chromatographic immunoassay. The test strip includes 1) a burgundy-colored conjugate pad containing mouse anti-methamphetamine antibodies coupled to colloidal gold; and 2) nitrocellulose membrane containing a Test (T) line and a Control (C) line. The Test line is coated with methamphetamine-BSA, and the Control line is coated with goat anti-rabbit IgG antibody.

This test is a competitive binding immunoassay. The methamphetamine in the urine specimen competes with the methamphetamine-BSA antigen coated on the nitrocellulose membrane for the limited binding sites of the conjugated anti-methamphetamine antibodies.

When an adequate amount of urine specimen is applied to the sample pad of the device, the urine specimen migrates by capillary action through the test strip. If the level of methamphetamine in the urine specimen is below the cutoff (1000 ng/ml), the Test line appears as a visible burgundy line. If the level of methamphetamine in the urine specimen is at or above the cutoff, no Test line develops.

The C line binds to the gold-conjugated rabbit IgG and forms a burgundy color line, regardless of the presence of methamphetamine.

REAGENTS AND MATERIALS SUPPLIED

- 50 test strips each sealed in a pouch with desiccant.
- 1 package insert (Instructions for Use).

MATERIALS REQUIRED BUT NOT PROVIDED

- Specimen collection containers
- Timer

STORAGE AND STABILITY

Store the kit at room temperature 15-30°C (59-86°F). Each device may be used until the expiration date printed on the label if it remains sealed in its foil pouch containing desiccant.

Do not freeze and/or expose the kit to temperatures over 30°C (86°F).



SPECIMEN COLLECTION

1. Each urine specimen must be collected in a clean container. Do not mix specimens.
2. Specimens may be kept at 15-30°C (59-86°F) for 8 hours, at 2-8°C for up to 3 days and at -20°C or lower for long term storage.

PRECAUTION

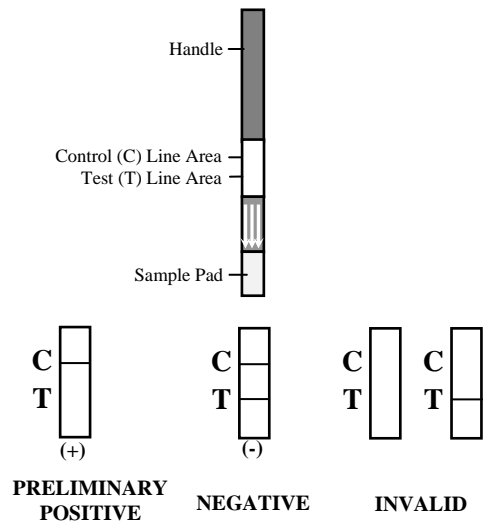
1. The instructions must be followed exactly to obtain accurate results.
2. Do not open the sealed pouch, unless ready to conduct the assay.
3. Do not use expired devices.
4. Dispose of all specimens and used assay materials as potentially biohazardous.

ASSAY PROCEDURE

1. Refrigerated specimens and other test materials, including devices, **must be equilibrated to room temperature before testing.**
2. Open the foil pouch at the notch and remove the test device.
3. Dip the device in the specimen for at least 10 seconds. Keep the specimen surface at the level indicated by the arrow sign on the device.
4. Remove the device from the specimen, and place it on a flat, dry surface.
5. Read the test result between four (4) to seven (7) minutes after adding the specimen.

INTERPRETATION OF RESULTS

IMPORTANT: Do not read test results after seven (7) minutes. The T Line should always be interpreted independently of the C Line.



Positive:

If only the C line appears, the test indicates that the methamphetamine level in the sample is at a cutoff of 1000 ng/ml or higher.

Samples with preliminary positive results should be confirmed with a more specific method before a positive conclusion is made.

Negative:

If both C line and T line appear, the test indicates that the methamphetamine level is below 1000 ng/ml.

Note: A very faint T line should be considered negative.

Invalid:

If no C line develops in 5 minutes, repeat the assay with a new test strip.

QUALITY CONTROL

• **Built-in Control Features**

This test contains a built-in control feature, the C line. The presence of the C line indicates that an adequate sample volume was used and that the reagents migrated properly. If the C line does not form, the test is considered invalid. In this case, review the whole procedure and repeat the test with a new device.

• **External Quality Control**

Users should always follow the appropriate federal, state, and local guidelines concerning the running of external quality controls. SAMHSA recommends that the concentration of drug(s) in positive and negative controls be approximately 25% above and below the cutoff concentration of the assay.

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LIMITATIONS

1. This test is for *professional in vitro* diagnostic use only.
2. Results obtained by this device provide only a preliminary qualitative result. A more specific alternate chemical method must be used in order to obtain a confirmed result.
3. This product is designed for testing human urine only.
4. Adulterants such as bleach or other strong oxidizing agents may produce erroneous test results if present in the sample. When suspected, collect a fresh specimen and repeat the test with a new device.
5. Samples in which bacterial contamination is suspected should not be used. These contaminants may interfere with the test and cause false results.

EXPECTED VALUES

This test is designed to detect methamphetamine in human urine at a cutoff concentration of 1000 ng/ml.

PERFORMANCE CHARACTERISTICS

1. Accuracy

A study was performed at three different Physician's Office Laboratories (POL) and a Reference Laboratory. One hundred (100) clinical samples were blind labeled and tested. Each sample was tested at each site, and compared with GC/MS results.

The results agreed 100% with the GC/MS data of specimens at levels below 75% of the cutoff (negative) and above the cutoff (positive). Twelve (12) discrepancies were observed on the specimens at level between 75% of the cutoff and the cutoff.

The overall agreement was 97%.

		MET 1000 Test		Total	Agreement
		Positive	Negative		
GC/MS (ng/ml)	Drug-free	0	200	200	100%
	<75% (0-750)	0	16	16	100%
	75%-Cutoff (750-1000)	12	12	24	50%
	Cutoff-125% (1000-1250)	24	0	24	100%
	Positive (>1250)	136	0	136	100%
Total		172	228	400	97%

2. Precision

Precision was determined by replicate assays on four different concentrations (GC/MS) of methamphetamine in urine samples: 0ng/ml, 870ng/ml (within 25% below the cutoff), 1200ng/ml (within 25% above the cutoff), and 2000ng/ml (positive) with three different production lots. The devices were tested for five consecutive days five times each, for a total of 25 assays for each control.

The results indicate 100% precision for the replicate within each lot and no appreciable inter-lot variation occurred across the three different lots of devices.

3. Cross-Reactivity

To determine the cross-reactivity of the structurally related compounds with the device, the following compounds were spiked into known drug-free urine pools and tested. Those compounds showed a positive response at the concentration indicated in the following table:

Description	Concentration (ng/ml)
<i>d</i> -Amphetamine	50,000
<i>l</i> -Amphetamine	10,000
3,4-methylenedioxyamphetamine (MDA)	50,000

4. Interference

To determine the interference of structurally unrelated compounds, the following analytes were spiked into known drug-free urine pools, as well as the methamphetamine positive (spiked with methamphetamine to the level of 1000 ng/ml) urine pools and were tested on the Methamphetamine Urine Test. No significant interference with either negative or positive results was observed at the concentrations listed below:

Compounds listed in this table found not to interfere with the test results at the concentration of 1mg/ml:












Acetaminophen	Codeine
Acetylsalicylic Acid	Cortisone
Amikacin	Dextromethorphan
Amitriptyline	Methadone
Ampicillin	Methanol
Arterenal	Oxalic Acid
Atropine	Penicillin-G (Benzylpenicillin)
Benzoic Acid	Pheniramine
Benzoyllecgonine	Phenylpropanolamine
Caffeine	Ranitidine
(+)-Chlorpheniramine	Salicylic Acid
(+/-)-Chlorpheniramine	Thioridazine
Cocaine	Trifluoperazine

Biological Analytes	Concentration
Albumin	2 mg/ml
Bilirubin	1 mg/ml
Creatine	1 mg/ml
Hemoglobin	1 mg/ml
Glucose	2 mg/ml
Vitamin C (L-Ascorbic Acid)	1 mg/ml
Uric Acid	1 mg/ml
pH	5.0-9.0

There is a possibility that other substances and/or factors not listed may interfere with the test and cause false results.

REFERENCES

- FDA Guidance for Labeling Urine Drugs of Abuse Screening Testing, Kshit Mohan, 7/21/87.
- Urine Testing for Drugs of Abuse. National Institute on Drug Abuse (NIDA): Research Monograph 73, 1986.
- Baselt, R.C. Disposition of Toxic Drugs and Chemicals in Man, 4th Ed., Biomedical Publ., Davis, CA; p475-477, 1995.
- Department of Health and Human Services, Mandatory Guidelines for Federal Workplace Drug Testing Programs, Fed. Register. p. 53 (69): 11970 (1988).
- Wilson, John, Abused Drugs II, a Laboratory Pocket Guide., AACC Press, Washington, DC; 1994.

	Temperature limitation		Use by YYYY-MM
	Batch/Lot code		<i>In vitro</i> diagnostic medical device
	Manufacturer		Catalog number
	Contains sufficient for < n > tests		Consult instructions for use
	Do not reuse		CE Mark
	Caution, consult accompanying documents		

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