

INSTANT-VIEW[®] Methamphetamine (500) Urine Test (Cassette) C €

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

INTENDED USE

This device is a qualitative immunoassay intended to be used to detect methamphetamine in human urine at a cutoff level of 500 ng/ml or higher. It is for use by health care professionals only.

The US Substance Abuse and Mental Health Services Administration (SAMHSA) recommends the screening level for methamphetamine to be a concentration of 1000 ng/ml.

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 is a potent sympathomimetic agent, central nervous system stimulating drug. It may induce alertness, wakefulness, increase energy, and suppress appetite. Overdose and extended usage of methamphetamine may lead to substance abuse, which may cause severe and/or permanent damage to the human nerve system. Studies indicated that about 40% of methamphetamine is excreted in urine without change. Therefore, methamphetamine in human urine has been widely used to detect the abuse of methamphetamine.

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 (500 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

- 25 test devices, each sealed in a pouch with a dropper pipette.
- 1 package insert (Instructions for Use).

MATERIAL 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.

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 combine 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

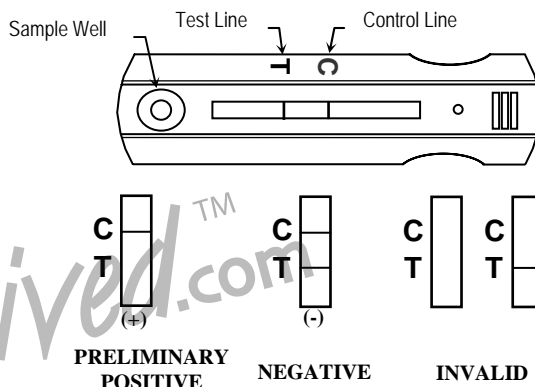
1. The instructions must be followed exactly to obtain accurate results.
2. Do not open the sealed pouch, unless ready to conduct the assay.
3. Do not use expired devices.
4. Dispose of all specimens and used assay materials as potentially biohazardous.

ASSAY PROCEDURE

1. Refrigerated specimens and other test materials, including devices, **must be equilibrated to room temperature before testing.**
2. Remove the test device from its pouch and place it on a flat surface. Label the device with specimen ID.
3. Holding the dropper vertically, add four drops of the specimen to the sample well.
4. 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 500 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 the C line and T line appear, the test indicates that the methamphetamine level is below 500 ng/ml.

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

Invalid:

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

QUALITY CONTROL

Built-in Control Features

This test contains a built-in control feature, the C line. The appearance of the burgundy C line indicates that an adequate volume of specimen has been absorbed and the capillary flow has occurred. If the C line does not develop within 5 minutes, the result is invalid. In this case, review the whole procedure and repeat 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 analytical 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 added in the device. 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 capable of detecting methamphetamine at a cutoff level of 500 ng/ml.

PERFORMANCE CHARACTERISTICS

1. Accuracy

A study was performed at three different Physician's Office Laboratories (POL) and a Reference Laboratory. One hundred nineteen (119) 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 125% of the cutoff (positive). Twenty three (23) discrepancies were observed on the specimens at level between 75% and 125% of the cutoff.

The overall agreement was 95.2%.

		MET 500 Test		Total	Agreement
		Positive	Negative		
GC/MS (ng/ml)	Drug-free	0	220	220	100%
	<75% (0-375)	0	36	36	100%
	75%-Cutoff (375-500)	6	22	28	78.6%
	Cutoff-125% (500-625)	23	17	40	57.5%
	Positive (>625)	152	0	152	100%
Total		181	295	476	95.2%

2. Precision

Precision was determined at the three different POL locations by persons with diverse educational backgrounds and work experience. Forty-pooled drug-free human urine specimens were spiked with methamphetamine at different levels. All specimens were blind labeled and tested. The result is as follows:

Methamp. Conc (ng/ml)	No of Samples	POL 1		POL 2		POL 3	
		+	-	+	-	+	-
0	8	0	8	0	8	0	8
375	8	1	7	0	8	1	7
500	8	8	0	8	0	8	0
625	8	8	0	8	0	8	0
1000	8	8	0	8	0	8	0

The results indicate a 98.3% concordance with the expected results.

3. Cross-Reactivity

A study was conducted using methamphetamine-related compounds to determine the cross-reactivity of the test.

Methamphetamine related compounds showing the lowest concentration of the drug producing a positive response equivalent to the cutoff level.

Description	Concentration (ng/ml)
d-Methamphetamine	500
l-Methamphetamine	25,000
d-Amphetamine	50,000
l-Amphetamine	10,000
3,4-methylenedioxymphetamine (MDA)	50,000

4. Interfering Substances

The following analytes, commonly found in urine, were spiked in urine pools containing 0, or 500 ng/ml methamphetamine and tested with the Methamphetamine Urine Test. No effects were observed from those analytes at 1.0 mg/ml.

Compounds tested and found not to cross-react with the result of the test at 0 ng/ml or 500 ng/ml methamphetamine in urine. (Concentration at 1.0 mg/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 (serum)	2,000 µg/ml
Bilirubin	1,000 µg/ml
Creatine	1,000 µg/ml
Hemoglobin	1,000 µg/ml
Glucose	2,000 µg/ml
Vitamin C (L-Ascorbic Acid)	1,000 µg/ml
Uric Acid	1,000 µg/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. Regist., 53 (69): 11970 (1988).

 15°C - 30°C	Temperature limitation		Use by YYYY-MM
 LOT	Batch/Lot code		In vitro diagnostic medical device
	Manufacturer		Catalog number
 Σ _n	Contains sufficient for < n > tests		Consult instructions for use
	For IVD performance evaluation only		Do not reuse
	Caution, consult accompanying documents		CE Mark

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