Atlas Medical CE

One Step
Methamphetamine Test Device (Urine) A rapid test for the qualitative detection of Methamphetamine in human urine.

IVD *For in vitro diagnostic use only.*

Store at (2-30º C)

INTENDED USE

The MET Rapid Test Device (Urine) is a rapid visual immunoassay for the qualitative, presumptive detection of Methamphetamine in human urine specimens at the cut-off concentrations listed below:

Parameter	Calibrator	Cut-off (ng/mL)
MET (Methamphetamine)	d-Methamphetamine	1000
MET (Methamphetamine)	d-Methamphetamine	500

INTRODUCTION

Methamphetamine is a strong central nervous system (CNS) stimulant that is mainly used as a recreational drug and less commonly as a treatment for attention deficit hyperactivity disorder and obesity.

Methamphetamine is taken orally, smoked, snorted, or dissolved in water or alcohol and injected. Smoking or injecting the drug delivers it very quickly to the brain, where it produces an immediate, intense euphoria. Because the pleasure also fades quickly, users often take repeated doses, in a "binge and crash" pattern.

The effects of Methamphetamine generally last 2-4 hours and the drug has a half-life of 9-24 hours in the body. In urines of normal pH approximately 43% of a dose is eliminated as unchanged methamphetamine in a 24hour period, with about 4-7% eliminated as amphetamine. Methamphetamine is generally detectable in the urine for 3-5 days, depending on urine pH level.

PRINCIPLE

The MET Rapid Test Device (Urine) detects Methamphetamine through visual interpretation of color development on the device. Drug conjugates are immobilized on the test region of the membrane. During testing, the specimen reacts with antibodies conjugated to colored particles and precoated on the sample pad. The mixture then migrates through the membrane by capillary action, and interacts with reagents on the membrane. If there are insufficient drug molecules in the specimen, the antibody-colored particle conjugate will bind to the drug conjugates, forming a colored band at the test region of the membrane. Therefore, a colored band appears in the test region when the urine is negative for the drug. If drug molecules are present in the urine above the cut-off concentration of the test, they compete with the immobilized drug conjugate on the test region for limited antibody binding sites. This will prevent attachment of the antibody-colored particle conjugate to the test region. Therefore, the absence of a colored band at the test region indicates a positive result. The appearance of a colored band at the control region serves as a procedural control, indicating that the proper volume of specimen has been added and membrane wicking has occurred.

MATERIALS

Materials Provided

- Test devices
- Disposable specimen droppers
- Package insert

Materials Required But Not Provided

- Specimen collection container
- Timer

PRECAUTIONS

- For in vitro diagnostic use only. Do not use after the expiration date.
- The test device 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 device should be discarded according to federal, state and local regulations.
- Avoid cross-contamination of specimens by using a new specimen collection container for each specimen obtained.

STORAGE AND STABILITY

- The kit can be stored at room temperature or refrigerated (2-30°C).
- The test device is stable through the expiration date printed on the sealed pouch.
- The test device must remain in the sealed pouch until use.
- Do not freeze.
- Do not use beyond the expiration date.

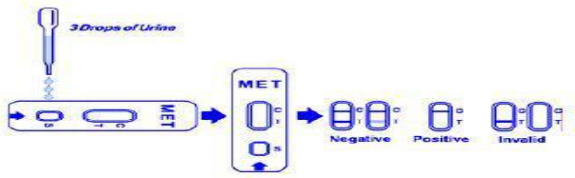
SPECIMEN COLLECTION AND PREPARATION

- The MET Rapid Test Device (Urine) is intended for use with human urine specimens only.
- Urine collected at any time of the day may be used.
- Urine specimens must be collected in clean, dry containers.
- Turbid specimens should be centrifuged, filtered, or allowed to settle and only the clear supernatant should be used for testing.
- Perform testing immediately after specimen collection. Do not leave specimens at room temperature for prolonged periods. Urine specimens may be stored at 2-8°C for up to 2 days. For long term storage, specimens should be kept below - 20°C.
- Bring specimens to room temperature prior to testing. Frozen specimens must be completely thawed and mixed well prior to testing. Avoid repeated freezing and thawing of specimens.
- If specimens are to be shipped, pack them in compliance with all applicable regulations for transportation of etiological agents.

PROCEDURE

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

1. Bring the pouch to room temperature before opening it. Remove the test device from the sealed pouch and use it as soon as possible.
2. Place the test device on a clean and level surface. Hold the dropper vertically and transfer 3 full drops of urine (approx. 120 l) to the specimen well (S) of the test device, and then start the timer. Avoid trapping air bubbles in the specimen well (S). See the illustration.
3. Wait for the red line(s) to appear. The result should be read at 5 minutes. Do not interpret the result after 8 minutes.



INTERPRETATION OF RESULTS

(Please refer to the illustration.)

NEGATIVE: Two lines appear. One red line should be in the control region (C), and another apparent red or pink line should be in the test region (T). This negative result indicates that the Methamphetamine concentration is below the detectable cut-off level.

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

POSITIVE: One red line appears in the control region (C). No line appears in the test region (T). This positive result indicates that the Methadone concentration exceeds the detectable cut-off level (300 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 using a new test device. If the problem persists, discontinue using the lot immediately and contact your local distributor.

QUALITY CONTROL

A procedural control is included in the test. A red line appearing in the control region (C) is considered an internal procedural control. It confirms sufficient specimen volume, adequate membrane wicking 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 practice to confirm the test procedure and to verify proper test performance.

LIMITATION

1. The MET One Step Methamphetamine Test Device (Urine) provides only a qualitative, preliminary analytical result. A secondary analytical method must be used to obtain a confirmed result. Gas chromatography/mass spectrometry (GC/MS) is the preferred confirmatory method.
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.

PERFORMANCE CHARACTERISTICS

Accuracy

The accuracy of the MET Rapid Test Device (Urine) was compared and checked against commercially available tests with a threshold value at the same cut-off levels. Urine samples taken from volunteers claiming to be non-users were examined under both tests. The results were >99.9% in agreement.

Reproducibility

The reproducibility of the MET Rapid Test Device (Urine) was verified by blind tests performed at four different locations. Samples with Methamphetamine

concentrations at 50% of the cut-off were all determined to be negative, while samples with Methamphetamine concentrations at 200% of the cut-off were all determined to be positive.

Precision

Test precision was determined by blind tests with control solutions. Controls with Methamphetamine concentrations at 50% of the cut-off yielded negative results, and controls with Methamphetamine concentrations at 150% of the cut-off yielded positive results.

Specificity

The following tables list the concentrations of compounds (ng/mL) above which the MET Rapid Test Device (Urine) identified positive results at 5 minutes

Methamphetamine 1000 related compounds	Concentration (ng/ml)
d-Methamphetamine	1,000
Chloroquine	25,000
Fenfluramine	12,500
l-Methamphetamine	10,000
Mephentermine hemisulfate salt	31,250
3,4-Methylenedioxyethylamphetamine	50,000
3,4-Methylenedioxy-methamphetamine	313
Paramethoxymethamphetamine	625
(-)-Ephedrine	4,000

Methamphetamine 500 related compounds	Concentration (ng/ml)
d-Methamphetamine	500
Chloroquine	12,500
Fenfluramine	12,500
l-Methamphetamine	3,125
Mephentermine hemisulfate salt	25,000
MDEA	12,500
MDMA	1,875
PMMA	625
(-)-Ephedrine	2,000

The following compounds were found not to cross-react when tested at concentrations at 100µg/ml.

(+)-Naproxen	Dextromethorphan	Pheniramine
4-Dimethyllaminoantiyrine	Dextrorphan tartrate	Phenothiazine
Acetaminophen (Except ACE)	Dopamine	Procaine
Acetone	Erythromycin	Protonix
Albumin	Ethanol	Pseudoephedrine
Amitriptyline (Except TCA)	Furosemide	Quinidine
Ampicillin	Glucose	Ranitidine
Aspartame	Guaiacol Glyceryl Ether	Sertraline
Aspirin	Hemoglobin	Tyramine
Benzocaine	Ibuprofen	Vitamin C (Ascorbic Acid)
Bilirubin	Imipramine (Except TCA)	Trimeprazine
b-Phenylethyl-amine	Isoproterenol	Venlafaxine
Caffeine	Lidocaine	Ibuprofen
Chloroquine	Methadone (Except MTD)	

REFERENCES

1. **Baselt RC. Disposition of Toxic Drugs and Chemicals in Man. 2nd ed. Davis: Biomedical Publications; 1982.**
2. **Hawks RL, Chiang CN, eds. Urine Testing for Drugs of Abuse. Rockville: Department of Health and Human Services, National Institute on Drug Abuse; 1986.**
3. **Substance Abuse and Mental Health Services Administration. Mandatory Guidelines for Federal Workplace Drug Testing Programs. 53 Federal Register; 1988.**
4. **McBay AJ. Drug-analysis technology--pitfalls and problems of drug testing. Clin Chem. 1987 Oct; 33 (11 Suppl): 33B-40B.**
5. **Gilman AG, Goodman LS, Gilman A, eds. Goodman and Gilman's The Pharmacological Basis of Therapeutics. 6th ed. New York: Macmillan; 1980.**

ATLAS MEDICAL
Ludwig-Erhard Ring 3
15827 Blankenfelde-Mahlow
Germany
Tel: +49 - 33708 – 3550 30
Email: Info@atlas-medical.com

PPI1694A01,Rev A (02.09.2019)

REF	Catalogue Number		Temperature limit
IVD	In Vitro diagnostic medical device		Caution
	Contains sufficient for <n> tests and Relative size		Consult instructions for use (IFU)
LOT	Batch code		Manufacturer
	Do not re-use		Use-by date
	Manufacturer fax number		Do not use if package i damaged
	Manufacturer telephone number		Date of Manufacture
	Keep away from sunlight		Keep dry