Atlas One Step Methamphetamine Test Strip (Urine)
A rapid, one step test for the qualitative detection of MET metabolites in human urine.

IVD **For *In vitro* diagnostic and professional use only**

Store at (2-30º C) CE

INTENDED USE
Atlas Methamphetamine Test Strip (Urine) is a lateral flow chromatographic immunoassay for the detection of Methamphetamine in human urine.
This assay provides only a preliminary analytical test result. A more specific alternate chemical method must be used in order to obtain a confirmed analytical result. Gas chromatography and 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.

INTRODUCTION
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 delaminated 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.
Atlas Methamphetamine Test Strip (Urine) 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 One Step Methamphetamine Test Strip (Urine) yields a positive result when the Methamphetamine in urine exceeds 1,000 ng/mL.

PRINCIPLE
Atlas Methamphetamine Test Strip (Urine) 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 1,000 ng/mL, will not saturate the binding sites of antibody coated particles in the test Strip. 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 exceeds 1,000 ng/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 that proper volume of specimen has been added and membrane wicking has occurred.

MATERIALS
Materials Provided
- Test Strips (contains mouse monoclonal anti-Methamphetamine antibody-coupled particles and Methamphetamine-protein conjugate. A goat antibody is employed in the control line system).
- Package insert

Materials Required But Not Provided
- Specimen collection container
- Timer

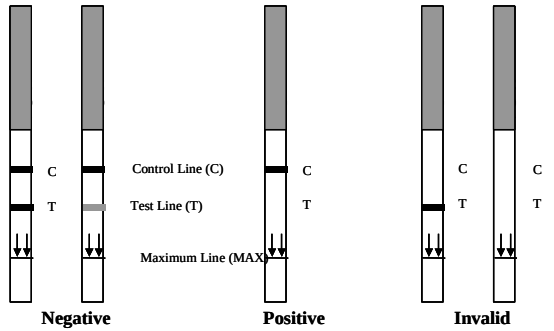
PRECAUTIONS
- For *in vitro* diagnostic use only. Do not use after the expiration date.
- The test Strip should remain in the sealed pouch until use.
- All specimens should be considered potentially hazardous and handled in the same manner as an infectious agent.
- The used test Strip should be discarded according to federal, state and local regulations.

STORAGE AND STABILITY
- The kit can be stored at room temperature or refrigerated (2-30°C).
- The test Cassette is stable through the expiration date printed on the label on the sealed pouch.
- The test Cassette 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 precipitates should be centrifuged, filtered, or allowed settle to obtain a clear supernatant for testing.

SPECIMEN STORAGE
- Urine specimens may be stored at 2-8°C for up to 48 hours prior to assay.
- For prolonged storage, specimens may be frozen and stored below -20°C.
- Frozen specimens should be thawed and mixed before testing.

PROCEDURE
Allow test Strip, 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 strip from the sealed pouch and use it as soon as possible.
2. With arrows pointing toward the urine specimen, immerse the test strip vertically in the urine specimen for at least 10-15 seconds. Do not pass the maximum line (MAX) on the test strip when immersing it. See the illustration above.
3. Place the test strip on a non-absorbent flat surface, start the timer and wait for the red line(s) to appear.
4. 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 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 level (1,000 ng/mL).

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 Methamphetamine concentration exceeds the detectable level (1,000 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 Strip. 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 positive 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 practice to confirm the test procedure and to verify proper test performance.

LIMITATION

- The MET One Step Methamphetamine Test Strip (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. 1,2
- 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.

PERFORMANCE CHARACTERISTICS

1. Accuracy

A side-by-side comparison was conducted using Atlas MET test strip (Urine) and commercially available drug rapid tests. Testing was performed on approximately 300 specimens previously collected from subjects presenting for Drug Screen Testing. Presumptive positive results were confirmed by GC/MS. The following results were tabulated:

% Agreement with Commercial Kit

	Positive Agreement	Negative Agreement	Total Results
MET	99%	100%	>99%

% Agreement with GC/MS

	Positive Agreement	Negative Agreement	Total Results
MET	100%	96%	98%

2. Analytical Sensitivity

A drug-free urine pool was spiked with MET at the following concentrations: 0 ng/mL,250 ng/mL, 375ng/mL, 750ng/mL and 625 ng/mL. The result demonstrates 100% accuracy at 50% above and 50% below the cut-off concentration.

Methadone Concentration (ng/mL)	Percent of Cut-off	n	Visual Result	
			Negative	Positive
0	0%	25	25	0
250	-50%	25	25	0
375	-25%	25	25	0
625	+25%	25	0	25
750	+50%	25	0	25

3. Analytical Specificity

The following table lists compounds that are positively detected in urine by the MET test Strip (Urine) at 5 minutes.

Methamphetamine 500	(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

REFERENCES

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

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REF	Catalogue Number		Temperature limit
IVD	*In Vitro* diagnostic medical device		Caution
Σ	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 is damaged
	Manufacturer telephone number		Date of Manufacture
	Keep away from sunlight		Keep dry