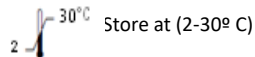


Atlas One Step Amphetamine Test Strip (Urine)

A rapid, one step test for the qualitative detection of
Amphetamine in human urine.

IVD For *in vitro* diagnostic use only.



INTENDED USE

Atlas One Step Amphetamine Test Strip (Urine) is a lateral flow chromatographic immunoassay for the detection of Amphetamine 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/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

Amphetamine is a Schedule II controlled substance available by prescription (Dexedrine) and is also available on the illicit market. Amphetamines are a class of potent sympathomimetic agents with therapeutic applications. They are chemically related to the human body's natural catecholamines: epinephrine and norepinephrine. 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 Amphetamines include increased blood pressure and cardiac arrhythmias. More acute responses produce anxiety, paranoia, hallucinations, and psychotic behavior. The effects of Amphetamines generally last 2-4 hours following use, and the drug has a half-life of 4-24 hours in the body. About 30% of Amphetamines are excreted in the urine in unchanged form, with the remainder as hydroxylated and deaminated derivatives. Use of an instrument. The test utilizes a monoclonal antibody to selectively detect elevated levels of Amphetamine in urine. Atlas One Step Amphetamine Test Strip (Urine) yields a positive result when Amphetamines in urine exceed 1,000 ng/mL.

Atlas One Step Amphetamine 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 Amphetamine in urine. Atlas One Step Amphetamine Test Strip (Urine) yields a positive result when Amphetamines in urine exceed 1,000 ng/mL.

PRINCIPLE

Atlas One Step Amphetamine Test Strip (Urine) is a rapid chromatographic 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. Amphetamine, if present in the urine specimen below 1,000 ng/mL, will not saturate the binding sites of the antibody-coated particles in the test strip. The antibody-coated particles will then be captured by immobilized Amphetamine 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 Amphetamine level exceeds 1,000 ng/mL because it will saturate all the binding sites of anti-Amphetamine antibodies.

A drug-positive urine specimen will not generate a colored line in the test line region, 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.

MATERIALS

Materials Provided

- Test strips (contain mouse monoclonal anti-Amphetamine antibody-coupled particles and Amphetamine-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 particles should be centrifuged, filtered, or allowed to settle to obtain clear specimen for testing.

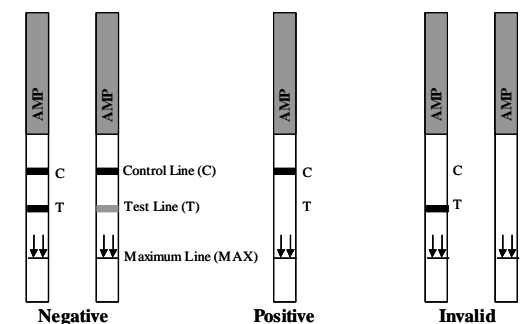
Specimen Storage

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.

PROCEDURE

Allow the 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 the strip. See the illustration below.
3. Place the test strip on a non-absorbent flat surface, start the timer and wait for the red line(s) to appear. 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 Amphetamine 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 Amphetamine 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 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.

LIMITATIONS

1. Atlas One Step Amphetamine 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) has been established as the preferred confirmatory method by the National Institute on Drug Abuse (NIDA). Clinical consideration and professional judgment should be applied to any test result, particularly when preliminary positive results are indicated.
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

A side-by-side comparison was conducted using Atlas One Step Amphetamine Test Strip (Urine) and a leading commercially available AMP rapid test. Testing was performed on 300 clinical specimens. Ten percent of the specimens employed were either at -25% or +25% level of the cut-off concentration of 1,000 ng/mL Amphetamine. Presumptive positive results were confirmed by GC/MS. The following results were tabulated:

Method		Other AMP Rapid Test		Total results
Atlas AMP	Results	141	0	141
	One Step	5	154	159
Test Strip	Negative	146	154	300
% Agreement with this rapid test Kit		97%	100%	98%

When compared at 1000ng/ml cut-off with GC/MS, the following results were tabulated:

Method		GC/MS		Total results
Atlas AMP	Results	132	9	141
	One Step	4	155	159
Test Strip	Negative	136	164	300
% Agreement with this rapid test Kit		97%	95%	96%

Analytical Sensitivity

A drug-free urine pool was spiked with Amphetamine at the following concentrations: 0 ng/mL, 500 ng/mL, 750 ng/mL, 1,000 ng/mL, 1,250 ng/mL and 1,500 ng/mL. The result demonstrates >99% accuracy at 50% above and 50% below the cut-off concentration. The data are summarized below:

AMP Concentration (ng/mL)	Percent of Cut-off	n	Visual	Result
			Negative	Positive
0	0	30	30	0
500	50%	30	30	0
750	75%	30	22	8
1,000	Cut-off	30	12	18
1,250	125%	30	2	28
1,500	150%	30	0	30

Analytical Specificity

The following table lists compounds that are positively detected in urine by Atlas One Step Amphetamine Test Strip (Urine) at 5 minutes.

















Compound	Concentration (ng/ml)	
D-Amphetamine	1,000	
D,L-Amphetamine sulfate	3,000	
L-Amphetamine	50,000	
(±) 3,4-MethylenedioxyAmphetamine	2,000	
Phentermine	3,000	
Digoxin	Naproxen	Triamterene
Diphenhydramine	Niacinamide	Tnfluoperazine
Doxylamine	Nifedipine	Tnmethopnm
Ecgonine hydrochloride	Norcodein	Tnmipramine
Ecgonine methylester	Norethindrone	D, L-Tryptophan
(l R, 2 S)-(-)- E p h e d r i n e	D-Norpropoxyphene	Tyramine
L-Ephedrine	Noscapine	D, L-Tyrosine
(-) Y Ephedrine	D, L-Octopa m i n e	Uric acid
Erythromycin	Oxalic acid	verapamil
(t-Estradiol	Oxazepam	Zomepirac

REFERENCES

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

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

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	Catalogue Number		Temperature limit
	In Vitro diagnostic medical device		Caution
	Contains sufficient for <n> tests and Relative size		Consult instructions for use (IFU)
	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