One Step
Amphetamine Test Strip (Urine)
Package Insert

REF 1182-S

A rapid, one step test for the qualitative detection of Amphetamine in human urine.
For professional in vitro diagnostic use only.

INTENDED USE

The AMP One Step Amphetamine Test Strip (Urine) is a lateral flow chromatographic immunoassay for the detection of Amphetamine in human urine at a cut-off concentration of 1,000 ng/mL. This test will detect other related compounds, please refer to the Analytical Specificity table in this package insert.

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.

SUMMARY

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.

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

PRINCIPLE

The AMP 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.

REAGENTS

The test strip contains mouse monoclonal anti-Amphetamine antibody-coupled particles and Amphetamine-protein conjugate. A goat antibody is employed in the control line system.

PRECAUTIONS

- For professional *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 local regulations.

STORAGE AND STABILITY

Store as packaged in the sealed pouch either at room temperature or refrigerated (2-30°C). The test strip is stable through the expiration date printed on the sealed pouch. The test strip 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.

MATERIALS

Materials Provided

- Test strips
- Package insert

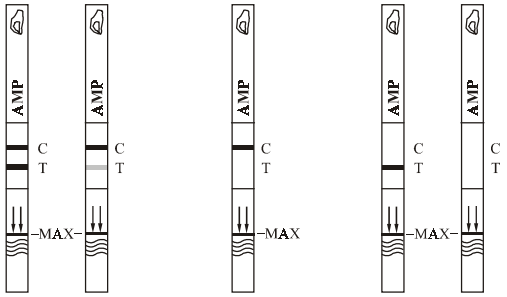
Materials Required But Not Provided

- Specimen collection container
- Timer

DIRECTIONS FOR USE

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 colored line(s) to appear. **Read results 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 colored line should be in the control line region (C), and another apparent colored line should be in the test line region (T). This negative result indicates that the Amphetamine concentration is below the detectable level (1,000 ng/mL).

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

POSITIVE: One colored line appears in the control line region (C). No line appears in the test line 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 colored line appearing in the control line 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. The AMP 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) is the preferred confirmatory method.[1,2]
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 the AMP One Step Amphetamine Test Strip (Urine) and a leading commercially available AMP rapid test. Testing was performed on 300 clinical specimens previously collected from subjects present for Drug Screen Testing. 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
AMP One Step Test Strip	Results	Positive	Negative	
	Positive	141	0	141
	Negative	5	154	159
Total Results		146	154	300
% Agreement		97%	>99%	98%

When compared at 1,000 ng/mL cut-off with GC/MS, the following results were tabulated:

Method		GC/MS		Total Results
AMP One Step Test Strip	Results	Positive	Negative	
	Positive	132	9	141
	Negative	4	155	159
Total Results		136	164	300
% Agreement		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:

Amphetamine Concentration (ng/mL)	Percent of Cut-off	n	Visual Result	
			Negative	Positive
0	0	30	30	0
500	-50%	30	30	0
750	-25%	30	22	8
1,000	Cut-off	30	12	18
1,250	+25%	30	2	28
1,500	+50%	30	0	30

Analytical Specificity

The following table lists compounds that are positively detected in urine by the AMP 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

Precision

A study was conducted at three physicians' offices by untrained operators using three different lots of product to demonstrate the within run, between run and between operator precision. An identical panel of coded specimens containing, according to GC/MS, no Amphetamine, 25% Amphetamine above and below the cut-off, and 50% Amphetamine above and below the 1,000 ng/mL cut-off was provided to each site. The results are given below:

Amphetamine Concentration (ng/mL)	n per Site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	15	15	0	15	0	15	0
500	15	15	0	15	0	14	1
750	15	13	2	11	4	11	4
1,250	15	6	9	4	11	4	11
1,500	15	2	13	1	14	1	14

Effect of Urinary Specific Gravity

Fifteen urine specimens of normal, high, and low specific gravity ranges were spiked with 500 ng/mL and 1,500 ng/mL of Amphetamine. The AMP One Step Amphetamine Test Strip (Urine) was tested in duplicate using the fifteen neat and spiked urine specimens. The results demonstrate that varying ranges of urinary specific gravity do not affect the test results.

Effect of Urinary pH

The pH of an aliquoted negative urine pool was adjusted to a pH range of 5 to 9 in 1 pH unit increments and spiked with Amphetamine to 500 ng/mL and 1,500 ng/mL. The spiked, pH-adjusted urine was tested with the AMP One Step Amphetamine Test Strip (Urine) in duplicate. The results demonstrate that varying ranges of pH does not interfere with the performance of the test.

Cross-Reactivity

A study was conducted to determine the cross-reactivity of the test with compounds in either drug-free urine or Amphetamine positive urine. The following compounds show no cross-reactivity when tested with the AMP One Step Amphetamine Test Strip (Urine) at a concentration of 100 µg/mL.

Non Cross-Reacting Compounds

4-Acetamidophenol	Creatinine	Ketoprofen	Procaine
Acetophenetidin	Deoxycorticosterone	Labetalol	Promazine
N-Acetylprocainamide	Dextromethorphan	Levorphanol	Promethazine
Acetylsalicylic acid	Diazepam	Loperamide	D,L-Propanolol
Aminopyrine	Diclofenac	Maprotiline	D-Propoxyphene
Amitryptyline	Diflunisal	Meperidine	D-Pseudoephedrine
Amobarbital	Digoxin	Meprobamate	Quinidine
Amoxicillin	Diphenhydramine	Methadone	Quinine
Ampicillin	Doxylamine	D-Methamphetamine	Ranitidine
L-Ascorbic acid	Ecgonine hydrochloride	L-Methamphetamine	Salicylic acid
Apomorphine	Ecgonine methylester	Methoxyphenamine	Secobarbital
Aspartame	(IR,2S)-(-)-Ephedrine	3,4-Methylenedioxyethyl-amphetamine	Serotonin
Atropine	L-Ephedrine	(+) 3,4-Methylenedioxy-methamphetamine	(5-Hydroxytyramine)
Benzilic acid	(-)-ψ-Ephedrine	Methylphenidate	Sulfamethazine
Benzoic acid	Erythromycin	Morphine-3-β-D-glucuronide	Sulindac
Benzoylecgonine	β-Estradiol	Nalidixic acid	Temazepam
Benzphetamine	Estrone-3-sulfate	Naloxone	Tetracycline
Bilirubin	Ethyl-p-aminobenzoate	Oxolinic acid	Tetrahydrocortisone, 3-Acetate
(±)-Brompheniramine	Fenfluramine	Oxycodone	Tetrahydrocortisone
Caffeine	Fenoprofen	Oxymetazoline	3-(β-D glucuronide)
Cannabidiol	Furosemide	Papaverine	Tetrahydrozoline
Cannabinol	Gentisic acid	Penicillin-G	Thebaine
Chloralhydrate	Hemoglobin	Pentazocine	Thiamine
Chloramphenicol	Hydralazine	Pentobarbital	Thioridazine
Chlordiazepoxide	Hydrochlorothiazide	Perphenazine	Tolbutamine
Chlorothiazide	Hydrocodone	Phencyclidine	Triamterene
(±) Chlorpheniramine	Hydrocortisone	Phenelzine	Trifluoperazine
Chlorpromazine	p-Hydroxyamphetamine	Phenobarbital	Trimethoprim
Chlorquine	O-Hydroxyhippuric acid	L-Phenylephrine	Trimipramine
Cholesterol	p-Hydroxymethamphetamine	β-Phenylethlamine	D, L-Tryptophan
Clomipramine	3-Hydroxytyramine	Phenylpropanolamine	Tyramine
Clonidine	Ibuprofen	Prednisolone	D, L-Tyrosine
Cocaine hydrochloride	Imipramine	Prednisone	Uric acid
Codeine	(±)-Isoproterenol	Procainamide	Verapamil
Cortisone	Isoxsuprine	Ketamine	Zomepirac
(-) Cotinine			

BIBLIOGRAPHY

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

Index of Symbols

	Storage Temperature		Manufacturer		Do not reuse
LOT	Lot Code	EC REP	Authorized Representative	IVD	For in vitro diagnostic use
	Expiration		Caution, see instructions	REF	Catalog No.

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