



AMP Rapid Test Cassette (Urine)

Package Insert

REF DAM-102 English

A rapid test for the qualitative detection of Amphetamine in human urine. For medical and other professional *in vitro* diagnostic use only.

INTENDED USE

The AMP Rapid Test Cassette (Urine) is a rapid chromatographic immunoassay for the detection of Amphetamine in human urine at a cut-off concentration of 1,000ng/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 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 Rapid Test Cassette (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 Amphetamines in urine. The AMP Rapid Test Cassette (Urine) yields a positive result when Amphetamines in urine exceed 1,000 ng/mL.

PRINCIPLE

The AMP Rapid Test Cassette (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. 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 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 proper volume of specimen has been added and membrane wicking has occurred.

REAGENTS

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

PRECAUTIONS

- For medical and other professional *in vitro* diagnostic use only. Do not use after the expiration date.
- The test 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 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 is stable through the expiration date printed on the sealed pouch. The test 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 assay. For long-term storage, specimens may be frozen and stored below -20°C. Frozen specimens should be thawed and mixed before testing.

MATERIALS

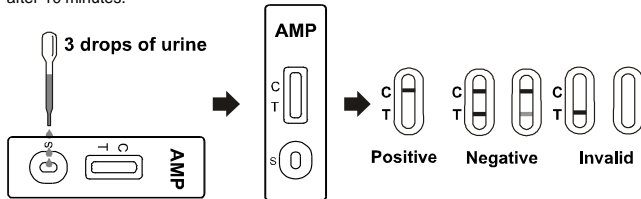
Materials Provided

- Test cassettes
- Droppers
- Package insert
- Materials Required But Not Provided
- Specimen collection containers
- Timer

DIRECTIONS FOR USE

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

- Bring the pouch to room temperature before opening it. Remove the test cassette from the sealed pouch and use it within one hour.
- Place the test cassette on a clean and level surface. Hold the dropper vertically and transfer 3 full drops of urine (approx. 120 µL) to the specimen well (S) of the test cassette, and then start the timer. Avoid trapping air bubbles in the specimen well (S). See the illustration.
- 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 colored lines appear. One colored line should be in the control line region (C), and another 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. 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 practice to confirm the test procedure and to verify proper test performance.

LIMITATIONS

- The AMP Rapid Test Cassette (Urine) provides only a qualitative, preliminary 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

Accuracy

A side-by-side comparison was conducted using the AMP Rapid Test Cassette and a commercially available AMP rapid test. Testing was performed on 100 clinical specimens previously collected from subjects present for Drug Screen Testing. The following results were tabulated:

Method	Other AMP Rapid Test		Total Results	
	Results	Positive		Negative
	AMP Rapid Test Cassette	Positive		33
	Negative	0	67	67
Total Results		33	67	100
% Agreement		>99.9%	>99.9%	>99.9%

A side-by-side comparison was conducted using the AMP Rapid Test Cassette and GC/MS at the cut-off of 1,000ng/mL. Testing was performed on 250 clinical specimens previously collected from subjects present for Drug Screen Testing. The following results were tabulated:

Method	GC/MS		Total Results	
	Results	Positive		Negative
	AMP Rapid Test Cassette	Positive		103

	Negative	2	142	144
Total Results		105	145	250
% Agreement		98.1%	97.9%	98.0%

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, 1,500 ng/mL and 3,000ng/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	26	4
1,000	Cut-off	30	15	15
1,250	+25%	30	3	27
1,500	+50%	30	0	30
3,000	3X	30	0	30

Analytical Specificity

The following table lists compounds that are positively detected in urine by the AMP Rapid Test Cassette (Urine) at 5 minutes.

Compound	Concentration (ng/mL)
D,L-Amphetamine sulfate	300
L-Amphetamine	25,000
(±) 3,4-Methylenedioxyamphetamine	500
Phentermine	1,000
Maprotiline	50,000
Methoxyphenamine	6,000
D-Amphetamine	1,000

Precision

A study was conducted at three hospitals 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	10	10	0	10	0	10	0
500	10	10	0	10	0	10	0
750	10	9	1	8	2	9	1
1,250	10	1	9	2	8	2	8
1,500	10	0	10	0	10	0	10

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 Rapid Test Cassette (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 Rapid Test Cassette (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 Rapid Test Cassette (Urine) at a concentration of 100 µg/mL.

Non Cross-Reacting Compounds













4-Acetamidophenol	Creatinine	Ketoprofen	Procaine
Acetophenetidin	Deoxycorticosterone	Labelalol	Promazine
N-Acetylprocainamide	Dextromethorphan	Loperanhol	Promethazine
Acetylsalicylic acid	Diazepam	Loperamide	D,L-Propranolol
Aminopyrine	Diclofenac	Maprotiline	D-Propoxyphene
Amitypyline	Diffunisol	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	(1R,2S)-(-)-Ephedrine	3,4-Methylenedioxyethylamphetamine	Serotonin
Atropine	L-Ephedrine	(5-Hydroxytryptamine)	
Benzilic acid	(-)-ψ-Ephedrine	(±)3,4-Methylenedioxy-methamphetamine	Sulfamethazine
Benzoic acid	Erythromycin		Sulindac

Benzoylcegonine	β-Estradiol	Methylphenidate	Temazepam
Benzphetamine	Estrone-3-sulfate	Morphine-3-β-D-glucuronide	Tetracycline
Bilirubin	Ethyl-p-aminobenzoate	Nalidixic acid	Tetrahydrocortisone, 3-Acetate
(±)-Brompheniramine	Fenfluramine	Naloxone	Tetrahydrocortisone, 3-(β-D glucuronide)
Caffeine	Fenopropfen	Oxolinic acid	Tetrahydrozoline
Cannabidiol	Furosemide	Oxycodone	Thebaine
Cannabinol	Gentisic acid	Oxymetazoline	Thiamine
Chloralhydrate	Hemoglobin	Papaverine	Thioridazine
Chloramphenicol	Hydralazine	Penicillin-G	Tolbutamine
Chlordiazepoxide	Hydrochlorothiazide	Pentazocine	Triamterene
Chlorothiazide	Hydrocodone	Pentobarbital	Trifluoperazine
(±) Chlorpheniramine	Hydrocortisone	Perphenazine	Trimethoprim
Chlorpromazine	p-Hydroxyamphetamine	Phencyclidine	Trimipramine
Chlorquine	O-Hydroxyhippuric acid	Phenelzine	D, L-Tryptophan
Cholesterol	p-Hydroxymethamphetamine	Phenobarbital	Tyramine
Clomipramine	3-Hydroxytyramine	L-Phenylephrine	D, L-Tyrosine
Clonidine	Ibuprofen	β-Phenylethylamine	Uric acid
Cocaine hydrochloride	Imipramine	Phenylpropanolamine	Verapamil
Codeine	(±)-Isoproterenol	Prednisolone	Zomepirac
Cortisone	Isoxsuprine	Prednisone	
(-) Cotinine	Ketamine		

【BIBLIOGRAPHY】

- 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.

Index of Symbols

	Consult instructions for use or consult electronic instructions for use		Contains sufficient for <n> tests		Temperature limit
	<i>In vitro</i> diagnostic medical device		Batch code		Catalogue number
	Authorized representative in the European Community/European Union		Use-by date		Do not re-use
	Do not use if package is damaged and consult instructions for use		Manufacturer		Caution

 **Hangzhou AllTest Biotech Co.,Ltd.**
 #550, Yinhai Street
 Hangzhou Economic & Technological Development Area
 Hangzhou, 310018 P.R. China
 Web: www.alltests.com.cn Email: info@alltests.com.cn



 **EC REP**
 MedNet EC-REP GmbH
 Borkstrasse 10,
 48163 Muenster,
 Germany

Number: 145010003
 Revision date: 2023-07-25