Amphetamine (AMP) Rapid Test (Urine)

Package Insert

Cat: AMP-U21 **Specimens:** Urine
Version: 1.1 **Effective Date:** 2025-08

For professional *in vitro* diagnostic use only.

INTENDED USE

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

PRINCIPLE

The Amphetamine (AMP) Rapid Test (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 Device. 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.

KIT COMPONENTS

Individually packed Test Devices	Each Device contains a strip with colored conjugates and reactive reagents pre-spreaded at the corresponding regions.
Disposable pipettes	For adding specimens use.
Package insert	For operation instruction.

MATERIALS REQUIRED BUT NOT PROVIDED

Specimen collection container	For specimens collection use.
Timer	For timing use.

PRECAUTIONS

- For professional *in vitro* diagnostic use only.
- Do not use after expiration date indicated on the package. Do not use the test if its foil pouch is damaged. Do not reuse tests.
- This kit contains products of animal origin. Certified knowledge of the origin and/or sanitary state of the animals does not totally guarantee the absence of transmissible pathogenic agents. It is therefore, recommended that these products be treated as potentially infectious, and handled observing the usual safety precautions (do not ingest or inhale).
- Avoid cross-contamination of specimens by using a new specimen collection container for each specimen obtained.
- Read the entire procedure carefully prior to performing any tests.
- Do not eat, drink or smoke in the area where the specimens and kits are handled. Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout the procedure and follow the standard procedures for proper disposal of specimens. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed.
- Humidity and temperature can adversely affect results.
- The used testing materials should be discarded in accordance with local, state and/or federal regulations.

STORAGE AND STABILITY

- The kit should be stored at 2-30°C until the expiry date printed on the sealed pouch.
- The test must remain in the sealed pouch until use.
- **Do not freeze.**
- Cares should be taken to protect components in this kit from contamination. Do not use if there is evidence of microbial contamination or precipitation. Biological contamination of dispensing equipments, containers or reagents can lead to false results.

SPECIMEN COLLECTION AND STORAGE

- 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.
- Collected urine specimens must be put in clear and dry containers.
- Perform the testing immediately after the specimen collection. Do not leave the specimens at room temperature for prolonged periods. Specimens may be stored at 2-8°C for up to 48 hours. 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.
- Pack the specimens in compliance with applicable regulations for transportation of etiological agents, in case they need to be shipped.

PROCEDURE

Allow the test device, urine specimen, and/or controls to equilibrate to room temperature (15 - 30℃) 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. 100 μL) to the specimen well (S) of the test device, and then start the timer. Avoid trapping air bubbles in the specimen well (S).
3. Wait for the red line(C) to appear. The result should be read at 5 minutes. Do not interpret the result after 10 minutes.

INTERPRETATION OF RESULTS

POSITIVE RESULT:



Only one colored band appears in the control region (C). No apparent colored band appears in the test region (T).

NEGATIVE RESULT:



Two colored bands appear on the membrane. One band appears in the control region (C) and another band appears in the test region (T).

INVALID RESULT:



Control band fails to appear. Results from any test which has not produced a control band at the specified reading time must be disgarded. Please review the procedure and repeat with a new test. If the problem persists, discontinue using the kit immediately and contact your local distributor.

NOTE:

1. The intensity of the color in test region (T) may vary depending on the concentration of aimed substances present in the specimen. Therefore, any shade of color in the test region should be considered negative. Besides, the concentration level can not be determined by this qualitative test.
2. Insufficient specimen volume, incorrect operation procedure, or performing expired tests are the most likely reasons for control band failure.

QUALITY CONTROL

- Internal procedural controls are not included in the test. A colored band appearing in the control region (C) is considered an internal positive procedural control. It confirms sufficient specimen volume and correct procedural technique.
- External controls are not supplied with this kit. It is recommended that positive and negative controls be tested as a good laboratory practice to confirm the test procedure and to verify proper test performance.

LIMITATIONS OF THE TEST

1. The Amphetamine (AMP) Rapid Test (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

A. Accuracy

The accuracy of the Amphetamine (AMP) Rapid Test (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.

B. Reproducibility

The reproducibility of the Amphetamine (AMP) Rapid Test (Urine) was verified by blind tests performed at four different locations. Samples with Amphetamine concentrations at 50% of the cut-off were all determined to be negative, while samples with Amphetamine concentrations at 200% of the cut-off were all determined to be positive.

C. Precision

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

D. Specificity

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

Amphetamine related 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

The following compounds yielded negative results up to a concentration of 100 μg/mL:

4-Acetamidophenol	Estrone-3-sulfate	Oxolinic acid
Acetophenetidin	Ethyl-p-aminobenzoate	Oxycodone
N-Acetylprocainamide	Fenfluramine	Oxymetazoline
Acetylsalicylic acid	Fenoprofen	Papaverine
Aminopyrine	Furosemide	Penicillin-G
Amitryptyline	Gentisic acid	Pentazocine
Amobarbital	Hemoglobin	Pentobarbital
Amoxicillin	Hydralazine	Perphenazine
Ampicillin	Hydrochlorothiazide	Phencyclidine
L-Ascorbic acid	Hydrocodone	Phenelzine
Apomorphine	Hydrocortisone	Phenobarbital
Aspartame	p-HydroxyAmphetamine	L-Phenylephrine

Atropine	O-Hydroxyhippuric acid	β-Phenylethlamine
Benzilic acid	p-Hydroxy-methAmphetamine	Phenylpropanolamine
Benzoic acid		Prednisolone
Benzoylecgonine	3-Hydroxytyramine	Prednisone
Benzphetamine	Ibuprofen	Procaine
Bilirubin	Imipramine	Promazine
(±) - Brompheniramine	(±) - Isoproterenol	Promethazine
Caffeine	Isoxsuprine	D,L-Propanolol
Cannabidiol	Ketamine	D-Propoxyphene
Cannabinol	Ketoprofen	D-Pseudoephedrine
Chloralhydrate	Labetalol	Quinidine
Chloramphenicol	Levorphanol	Quinine
Chlordiazepoxide	Loperamide	Ranitidine
Chlorothiazide	Maprotiline	Salicylic acid
(±) Chlorpheniramine	Meperidine	Secobarbital
Chlorpromazine	Meprobamate	Serotonin (5-Hydroxytyramine)
Chlorquine	Methadone	Sulfamethazine
Cholesterol	D-methAmphetamine	Sulindac
Clomipramine	(L)-methAmphetamine	Temazepam
Clonidine	Methoxyphenamine	Tetracycline
Cocaine hydrochloride	3,4-Methylenedioxyethyl-Amphetamine	Tetrahydrocortisone, 3 Acetate
Codeine	(+) 3,4-Methylenedioxy-methAmphetamine	Tetrahydrocortisone 3 (β-D glucuronide)
Cortisone	Methylphenidate	Tetrahydrozoline
(-) Cotinine	Morphine-3-β-D-glucuronide	Thebaine
Creatinine	Nalidixic acid	Thiamine
Deoxycorticosterone	Naloxone	Thioridazine
Dextromethorphan	Naltrexone	Tolbutamine
Diazepam	Naproxen	Triamterene
Diclofenac	Niacinamide	Trifluoperazine
Diflunisal	Nifedipine	Trimethoprim
Digoxin	Norcodein	Trimipramine
Diphenhydramine	Norethindrone	D, L-Tryptophan
Doxylamine	D-Norpropoxyphene	Tyramine
Ecgonine hydrochloride	Noscapine	D, L-Tyrosine
Ecgonine methylester	D,L-Octopamine	Uric acid
(IR,2S)-(-)-Ephedrine	Oxalic acid	Verapamil
L-Ephedrine	Oxazepam	Zomepirac
(-)-ψ- Ephedrine		
Erythromycin		
β-Estradiol		

LITERATURE 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

Index of Symbols

	Do not re-use	IVD	In vitro diagnostic medical device
	Temperature limit		Consult instruction for use
	Caution	LOT	Batch code
	Use-by date	Σ	Contains sufficient for <n> tests
	Keep away from sunlight		Manufacturer
	Keep dry	CE	European Conformity symbol The symbol should be affixed after the approval of the Competent Authority
	Do not use if package is damaged and consult instructions for use		
EU REP	Authorized representative in the European Community/European Union		

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