Amphetamine (AMP) Rapid Test

REF: ABH-IC09-AMP

INTENDED USE:

The amphetamine (AMP) Rapid Test is an easy, rapid, and visually read screening chromatographic immunoassay method. The assay employs specific monoclonal antibodies to selectively identify amphetamine and its metabolites in urine with a high degree of sensitivity. It has been developed for the determination of morphine in urine at a concentration of 500 ng/mL.

TEST PRINCIPLE:

The AMP Rapid Test is an immunoassay based on the principle of competitive binding. Drugs that 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 500 ng/ml, will not saturate the binding sites of the coated antibody in the test line (T). The coated antibody 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 is at or above 500 ng/mL because it will saturate all the binding sites of anti-amphetamine antibodies. To serve as a procedural control, a colored line will always appear in the control (C) line region, indicating that the proper volume of specimen has been added and membrane wicking has occurred.

COMPONENTS:

The kit component configurations are provided below:

Test Strip (200 Pcs) and IFU.

STORAGE AND STABILITY:

-Store the kit at 2-30˚C. If stored at 2-8˚C, ensure that the test device is brought to 15-30˚C before opening. The test kit is valid for 18 months.

- Do not freeze the kit or store the kit over 30˚C.

SPECIMEN COLLECTION AND PREPARATION:

- The urine specimen can be collected at any time of day in a clean and dry container.
- Urine specimens with visible particles should be centrifuged, filtered, or allowed to precipitate.

SPECIMENS STORAGE:

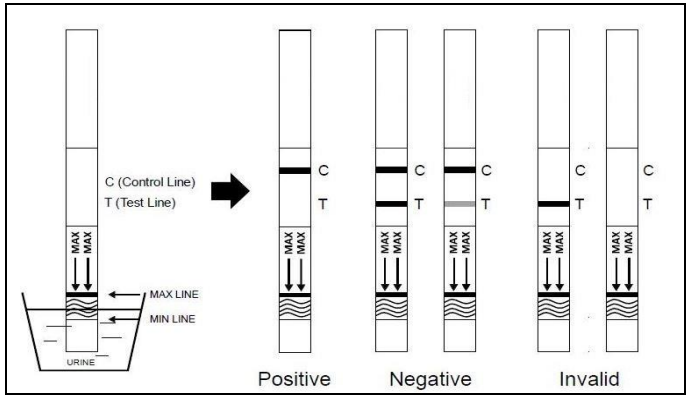
- Sample should be tested immediately after collection. If testing will be delayed, samples may be stored up to 48 hours at 2~8°C or stored at -20°C for long-term storage.
- Refrigerated or frozen specimens should reach room temperature prior to testing. Frozen specimens must be completely thawed and mixed well prior to testing. Specimens should not be frozen and thawed repeatedly.

TEST PROCEDURE:

1. Allow the test device and specimens to equilibrate to temperature prior to testing.
2. Remove the test device from the sealed pouch just prior to the testing and lay it flat on the workbench.
3. With arrows pointing toward the urine specimen, immerse the test strip vertically in the urine specimen for at least 10-30 seconds. Do not pass the maximum line (MAX) on the test strip when immersing the strip. See the illustration below. Or transfer 3 drops of samples (100 µL) to the sample part of the test results.
4. Wait for the colored band(s) to appear. The result should be read in 3-10 minutes. Do not interpret the result after 15 minutes.

INTERPRETATION OF ASSAY RESULTS:

- Negative: When both the C and T line develop.
- Positive: When only the C line develops. No apparent colored line appears in theT line.
- Invalid: If the C Line does not appear, the assay is invalid regardless of whether the color of the T line is present. Repeat the assay with a new device.



PERFORMANCE CHARACTERISTICS:

Clinical Sensitivity and Specificity

The MOP Rapid Test has been evaluated with specimens obtained from patients. A commercialized assay based on GC/MS was used as the reference method. The results show that the MOP Rapid Test has high overall accuracy.

Relative Sensitivity: 98.5%

Relative Specificity: 97.6%

Accuracy: 98%

Cross-reactivity and Interference

Compounds not detected less than 100 µg/mL: Acetaminophen, Acetophenetidin, N-Acetylprocainamide, Acetylsalicylic acid, Aminopyrine, Amoxicillin, Ampicillin, L-Ascorbic acid, Apomorphine, Aspartame, Atropine, Benzilic acid, Benzoic acid, Benzphetamine, Bilirubin, D/L-Brompheniramine, Caffeine, Cannabidol, Chloralhydrate, Chloramphenicol, Chlorothiazide, D/L-Chloropheniramine, Chlorpromazine, Chloroquine, Cholesterol, Clonidine, Cortisone, L-Cotinine, Creatinine, Deoxycorticosterone, Dextromethorphan, Diclofenac, Diflunisal, Digoxin, Diphenhydramine, Ecgonine methyl ester, L -Ψ-Ephedrine, β-Estradiol, Estrone-3-sulfate, Ethyl-p-aminobenzoate, [1R,2S] (-) Ephedrine, L(–)-Epinephrine, Erythromycin, Fenoprofen, Furosemide, Gentisic acid, Hemoglobin, Hydralazine,

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Hydrochlorothiazide, Hydrocortisone, O-Hydroxyhippuric acid, p-Hydroxyamphetamine, p-Hydroxytyramine, Ibuprofen, Iproniazid, D/L-Isoproterenol, Isoxsuprine, Ketamine, Ketoprofen, Labetalol, Loperamide, Meperidine, Meprobamate, Methoxyphenamine, Methylphenidate, Nalidixic acid, Naloxone, Naltrexone, Naproxen, Niacinamide, Nifedipine, Norethindrone, D-Norpropoxyphene, Noscapine, D/L-Octopamine, Oxalic acid, Oxolinic acid, Oxymetazoline, Papaverine, Penicillin-G, Pentazocine hydrochloride, Perphenazine, Phenelzine, L-Phenylephrine, β-Phenylethylamine, Prednisolone, Prednisone, D/L-Propranolol, D-Propoxyphene, D-Pseudoephedrine, Quinacrine, Quinine, Quindine, Ranitidine, Salicylic acid, Serotonin, Sulfamethazine Sulindac Tetracycline Thiamine Thioridazine D/L-Tyrosine, Tolbutamide, Triamterene, Trifluoperazine, Trimethoprim, Tryptamine, D/L-Tryptophan, Tyramine, Uric acid, Verapamil Zomepirac, Tetrahydrocortisone, 3 (β-D-glucuronide).

ANALYTICAL SPECIFICITY:

The following compounds with a similar chemical structure yielded a positive result at the specified concentration:

AMP Rapid Test	Concentration (ng/mL)
D-Amphetamine	1000
D,L-Amphetamine sulfate	3000
L-Amphetamine	50,000
(±)3,4-Methylenedioxyamphetamine	2000
Phentermine	3000

WARNINGS:

1. This instruction of use (IFU) must be read completely before performing the test. Failure to follow directions in IFU may yield inaccurate test results.
2. Test results should be read 10 minutes after a specimen is applied to the sample well. Results read after 15 minutes may give erroneous results.
3. Do not open the sealed pouch until you are ready to conduct the assay. Once opened, the cassettes should be used within 30 min.
4. Do not use expired devices.
5. Bring the test and samples to room temperature (15-30°C) before use.
6. Wear protective clothing and disposable gloves while handling the kit reagents and clinical specimens. Wash hands thoroughly after performing the test.
8. Dispose of all specimens and materials used to perform the test as biohazardous waste.

LIMITATIONS OF THE PROCEDURE:

1. This test is for health care professionals to use.
2. There is no meaning in the lines' color intensity.
3. The final diagnosis should be made by the physician's clinical findings and test results.

REFERENCES:

1. Baselt RC. Disposition of Toxic Drugs and Chemicals in Man. 6th Ed.Biomedical Publ., Davis, CA. 2002; 129.

2. FDA Guidance Document: Guidance for Premarket Submission for Kits for Screening Drugs of Abuse to be Used by the Consumer, 1997.
3. A Handbook of Drug and Alcohol Abuse, Gail Winger, Third Edition, Oxford Press, 1992, page 146.
4. Tietz NW. Textbook of Clinical Chemistry. W.B. Saunders Company.1986; 1735.
5. Hawks RL, CN Chiang. Urine Testing for Drugs of Abuse. National Institute for Drug Abuse (NIDA), Research Monograph 73, 1986.

Index of CE Symbols:

	Use by date		Consult instructions for use
	Contains sufficient for tests		Caution
	Date of Manufacture		Manufacturer
	In vitro diagnostic medical device		Temperature limit
	Batch Code		Do not re use
	Catalog Number		Do not use if package is damaged
	Keep dry		Keep away from sunlight

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