AMP Rapid Test Cassette
(Whole Blood/Serum/Plasma)
Package Insert

A rapid test for the qualitative detection of Amphetamine in human whole blood or serum or plasma.
For medical and other professional in vitro diagnostic use only.

【INTENDED USE】

The AMP Rapid Test Cassette (whole blood/serum/plasma)is a lateral flow chromatographic immunoassay for the detection of Amphetamine in whole blood or serum or plasma at a cut-off concentration of 80ng/ml. This test will detect other related compounds, please refer to the analytical Specificity table in this package insert.

This assay provides only a qualitative, preliminary analytical test result. A more specific alternate chemical method must be used in order to obtain a confirmedanalytical result. Gas chromatographymass 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 whole blood or serum or plasma in unchanged form, with the remainder as hydroxylated and deaminated derivatives[1].

【PRINCIPLE】

The AMP Rapid Test Cassette(whole blood/serum/plasma) is an immunoassay based on the principle of competitive binding. Drugs that may be present in the whole blood/serum/plasma specimen compete against the drug conjugate for binding sites on the antibody.

During testing, a whole blood/serum/plasma specimen migrates upward by capillary action. Amphetamine, if present in the whole blood/serum/plasma specimen below the cut-off level, will not saturate the binding sites of the antibody in the test. The antibody coated particles will then be captured by immobilized Amphetamine-protein 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 the cut-off level because it will saturate all the binding sites of anti- Amphetamine antibodies.

A drug-positive whole blood/serum/plasma specimen will not generate a colored line in the test line region because of drug competition, while a drug-negative whole blood/serum/plasma 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 controlline 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 controlline system.

【PRECAUTIONS】

- For professional in vitro diagnostic use only. Do not use after the expiration date.
- Do not eat, drink or smoke in the area where the specimens or kits are handled.
- Do not use test if pouch is damaged
- Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout testing and follow the standard procedures for proper disposal of specimens.
- Wear protective clothing such as laboratory coats, disposable gloves and eye protection whenspecimens are being tested.
- The used test should be discarded according to local regulations.
- Humidity and temperature can adversely affect results.

【STORAGE AND STABILITY】

Store as packaged in the sealed pouch at room temperature or refrigerated (2-30°C). The test is stablethrough the expiration date printed on the sealed pouch. The test must remain in the sealed pouch untiluse. **DO NOT FREEZE**. Do not use beyond the expiration date.

【SPECIMEN COLLECTION AND PREPARATION】

- The AMP Rapid Test Cassette can be performed using whole blood (from venipuncture or fingerstick) or serum or plasma.
- To collect **Fingerstick Whole blood specimens**:
  - Wash the patient's hand with soap and warm water or clean with an alcohol swab. Allow to dry.
  - Massage the hand without touching the puncture site by rubbing down the hand towards the fingertip of the middle or ring finger.
  - Puncture the skin with a sterile lancet. Wipe away the first sign of blood.
  - Gently rub the hand from wrist to palm to finger to form a rounded drop of blood over the puncture site.
  - Add the FingerstickWhole blood specimen to the test by using **a capillary tube**:
    - Touch the end of the capillary tube to the blood until filled to approximately 40 μl. Avoid air bubbles.
    - Place the bulb onto the top end of the capillary tube, then squeeze the bulb to dispense the whole blood to the specimen area of the test cassette.
- Testing should be performed immediately after the specimens have been collected. Do not leave the specimens at room temperature for prolonged periods. For long term storage, specimens should be kept below -20°C. Whole blood or serum or plasma collected by venipuncture should be stored at 2-8°C if the test is to be run within 2 days of collection. Do not freeze whole blood or serum or plasma specimens. Whole blood/serum/plasma collected by fingerstick should be tested immediately.
- Bring specimens to 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.
- If specimens are to be shipped, they should be packed in compliance with local regulations covering the transportation of etiologic agents.

【MATERIALS】

Materials Provided

• Test cassettes • Droppers • Buffer • Package insert

Materials Required But Not Provided

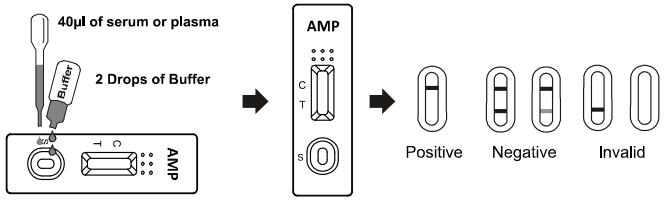
• Specimen collection containers • Centrifuge
•lancets (for fingerstick whole blood only) • Timer
•Heparinized capillary tubes and dispensing bulb (for fingerstick whole blood only)

【DIRECTIONS FOR USE】

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

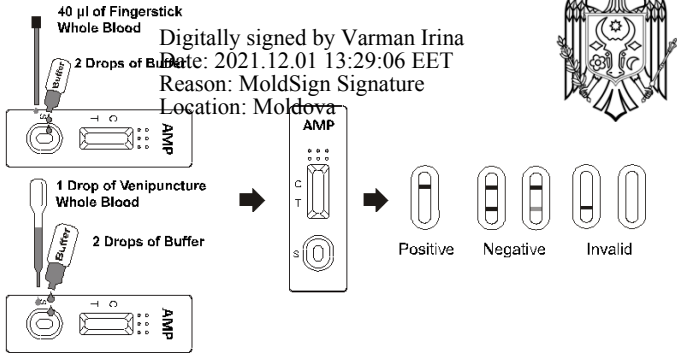
For serum or plasma specimen:

1. Bring the pouch to room temperature (15-30℃) before opening it. Remove the cassette from the sealed pouch and use it within one hour.
2. Place the cassette on a clean and level surface. Hold the dropper vertically and transfer **1 full drop of serum or plasma** (approximately 40ul), then add **2 drops of buffer** (approximately 80 μl) to the specimen well of the cassette, and then start the timer. Avoid trapping air bubbles in the specimen well. See illustration below.
3. Wait for the colored line(s) to appear. **Read the result at 5 minutes.** Do not interpret the result after 10 minutes.



For whole blood specimen:

1. Bring the pouch to room temperature before opening it. Remove the test cassette from the sealed pouch and use it as soon as possible.
2. Place the cassette on a clean and level surface.
   For **Venipuncture Whole blood specimen:**
   Hold the dropper vertically and transfer **1 drop of whole blood** (approximately 40μl) to the specimen well, then **add 2 drops of buffer** (approximately 80 μl), and start the timer. See illustration below.
   For Fingerstick Whole blood specimen:
   - To use a capillary tube: Fill the capillary tube and **transfer approximately 40μl of fingerstick whole blood specimen** to the specimen area of test cassette, then add **2 drops of buffer**(approximately 80 μl) and start the timer. See illustration below.
3. 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 controlline 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 cut-off level.

***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 controlline region (C). No line appears in the test line region (T). This positive result indicates that the Amphetamine concentration exceeds the detectable cut-off level.

INVALID: Controlline fails to appear. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for controlline failure. Review the procedure and repeat the test with a new test. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

【QUALITY CONTROL】

A procedural control is included in the test. A colored line appearing in the control region (C) is the internal procedural control. It confirms sufficient specimen volume and correct procedural technique. Control standards are not supplied with this kit; however, 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】

1. The AMP Rapid Test Cassette (Whole blood /Serum/Plasma) 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.[2]
2. It is possible that technical or procedural errors, as well as other interfering substances in the whole blood or serum or plasma specimen may cause erroneous results.
3. A positive result indicates presence of the drug or its metabolites but does not indicate level of intoxication, administration route or concentration in whole blood or serum or plasma.
4. A negative result may not necessarily indicate drug-free Whole blood/serum/plasma. Negative results can be obtained when drug is present but below the cut-off level of the test.
5. Test does not distinguish between drugs of abuse and certain medications.

【EXPECTED VALUES】

This negative result indicates that the Amphetamine concentration is below the detectable level of 80ng/ml. Positive result means the concentration of Amphetamine is above the level of 80ng/ml. The AMP Rapid Test Cassette has a sensitivity of 80ng/ml

【PERFORMANCE CHARACTERISTICS】

Accuracy

A side-by-side comparison was conducted using The AMP Rapid Test Cassette and GC/MSat the cut-off of 80ng/ml. Testing was performed on 90 clinical specimens previously collected from subjects present for Drug Screen Testing. The following results were tabulated:

Clinic Result of Whole Blood

Method		GC/MS		Total Results
AMP Rapid Test Cassette	Results	Positive	Negative	
	Positive	20	1	21
	Negative	1	68	69
Total Results		21	69	90
% Agreement		95.2%	98.6%	97.8%

Clinic Result of Serum or Plasma

Method		GC/MS		Total Results
AMP Rapid Test Cassette	Results	Positive	Negative	
	Positive	20	1	21
	Negative	1	68	69
Total Results		21	69	90
% Agreement		95.2%	98.6%	97.8%

Analytical Sensitivity

A drug-free whole blood/serum/plasma pool was spiked with Amphetamine at the following concentrations of ±50%cutoff and 3x cutoff,The data are summarized below:

For whole blood:

AMP Concentration (ng/ml)	Percent of Cut-off	n	Visual Result	
			Negative	Positive
0	0	30	30	0
40	-50%	30	30	0
80	Cut-off	30	15	15
120	+50%	30	0	30
240	3X	30	0	30

For serum or plasma:

AMP Concentration (ng/ml)	Percent of Cut-off	n	Visual Result	
			Negative	Positive
0	0	30	30	0
40	-50%	30	30	0
80	Cut-off	30	15	15
120	+50%	30	0	30
240	3X	30	0	30

Analytical Specificity

The following table lists compounds that are positively detected in Whole blood/Serum/Plasma by The AMP Rapid Test Cassette (Whole blood/Serum/Plasma) at 5 minutes.

Compound	Concentration (ng/ml)
D,L-Amphetamine sulfate	20
L-Amphetamine	3,000
(±) 3,4-Methylenedioxyamphetamine	40
Phentermine	150
Maprotiline	6,000
Methoxyphenamine	1,500
D-Amphetamine	80

Precision

A study was conducted at three hospitals 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 no Amphetamine, and 50% Amphetamine above and below the 80ng/ml cut-off was provided to each site. The following results were tabulated:

AMP Concentration (ng/ml)	n per Site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	10	10	0	10	0	10	0
40	10	8	2	9	1	9	1
120	10	1	9	1	9	2	8

Cross-Reactivity

A study was conducted to determine the cross-reactivity of the test with compounds in either drug-free whole blood/serum/plasma or Amphetamine positive whole blood/serum/plasma. The following compounds show no cross-reactivity when tested with The AMP Rapid Test Cassette(whole blood/serum/plasma) 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	Ecgoninemethylester	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 3-(β-D glucuronide)
Caffeine	Fenoprofen	Oxymetazoline	Tetrahydrozoline
Cannabidiol	Furosemide	Papaverine	Thebaine
Cannabinol	Gentisic acid	Penicillin-G	Thiamine
Chloralhydrate	Hemoglobin	Pentazocine	Thioridazine
Chloramphenicol	Hydralazine	Perphenazine	Tolbutamine
Chlordiazepoxide	Hydrochlorothiazide	Phenelzine	Triamterene
Chlorothiazide	Hydrocodone	Prochlorperazine	Trifluoperazine

(±) Chlorpheniramine	Hydrocortisone	Pentobarbital	Triamterene
Chlorpromazine	p-Hydroxyamphetamine	Perphenazine	Trifluoperazine
Chlorquine	O-Hydroxyhippuric acid	Phencyclidine	Trimethoprim
Cholesterol	p-Hydroxymethamphetamine	Phenelzine	Trimipramine
Clomipramine	3-Hydroxytyramine	Phenobarbital	D, l-Tryptophan
Clonidine	Ibuprofen	l-Phenylephrine	Tyramine
Cocaine hydrochloride	Imipramine	β-Phenylethlamine	D, l-Tyrosine
Codeine	(±)-Isoproterenol	Phenylpropanolamine	Uric acid
Cortisone	Isoxsuprine	Prednisolone	Verapamil
(-) Cotinine	Ketamine	Prednisone	Zomepirac
4-Acetamidophenol	Creatinine	Ketoprofen	Procaine

Interfering Substances

The AMP Rapid Test Cassette (Whole blood /Serum/Plasma) has been tested for possible interferencefrom visibly hemolyzed and lipemic specimens. In addition, no interference was observed in specimens containing up to 100 mg/dl hemoglobin;up to 100 mg/dl bilirubin; and up to 200 mg/dl human serum albumin.

【BIBLIOGRAPHY】

1. Tietz NW. Textbook of Clinical Chemistry. W.B. Saunders Company. 1986; 1735
2. Baselt RC. Disposition of Toxic Drugs and Chemicals in Man.2nd Ed. Biomedical Publ., Davis, CA. 1982; 488

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