RAPID AMPHETAMINE TEST

FOR THE QUALITATIVE ASSESSMENT OF AMPHETAMINE IN HUMAN URINE

Catalog Number: 1L01S3, 1L01C3

For In Vitro Diagnostic and Forensic Use Only

INTENDED USE

Rapid AMP Test is an immunochromatography based one step in vitro test. It is designed for qualitative determination of amphetamines in human urine specimens.

This assay provides only a preliminary analytical test result. A more specific alternative chemical method must be used in order to obtain a confirmed analytical result. Gas chromatography/ mass spectrometry (GC/MS) has been established as the preferred confirmatory method by the Substance Abuse Mental Health Services Administration (SAMHSA). Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are indicated.

SUMMARY AND EXPLANATION

Amphetamines are a class of potent sympathominetic agents with therapeutic applications. The most common amphetamines are d-amphetamine and d,l-amphetamine. Amphetamines are central nervous stimulants that cause the neutrotransmitters epinephrine, norepinephrine and dopamine to be released into the brain and body giving users feelings of euphoria, alertness, and increased energy. Chronic abuse of amphetamine leads to tolerance and drug reinforcement effect. Cardiovascular responses to amphetamine include increased blood pressure and cardiac arrhythmias. More acute responses produce anxiety, paranoia, hallucinations and psychotic behavior. Amphetamine is metabolized by a number of pathways. In general, acid urine promotes excretion whereas alkaline urine retards it. In 24 hours, approximately 79% of the amphetamine dose is excreted in acid urine and about 45% in alkaline urine. Typically, about 20% is excreted as unchanged amphetamine. Unchanged amphetamine can be detected up to 1 –2 days after use.

PRINCIPLE

Rapid AMP Test is based on the principle of specific immunochemical reaction between antibodies and antigen to analyze particular compound in human urine specimen. The assay relies on the competition for binding antibody. When drug is present in the urine specimen, it competes with drug conjugate for the limited amount of antibody-dye conjugate. When the amount of drug is equal or more than the cut-off, it will prevent the binding of drug conjugate to the antibody. Therefore, a positive urine specimen will not show a colored band on the test line zone, indicating a positive result, while the presence of a colored band indicates a negative result.

A control line is present in the test window to work as procedural control. This colored band should always appear on the control line zone if the test device is stored in good condition and the test is performed appropriately.

MATERIAL PROVIDED

1. Rapid AMP Test. The amount of each coated antigen and/or antibody on the strip is less than 1.0 mg for antigen conjugate and is less than 1.0 mg for goat anti-rabbit IgG antibody.
   Test zone: contains drug bovine protein antigen conjugates
   Control zone: contains Goat anti-rabbit IgG antibody
   Conjugate pad: contains anti-drug antibody.
2. Instruction for use.

MATERIAL REQUIRED BUT NOT PROVIDED

1. Urine collection container.
2. Timer or clock.

STORAGE AND STABILITY

The test device should be stored at 4 to 30℃ and will be effective until the expiration date stated on the package. The product is humidity -sensitive and should be used immediately after being open. Any improperly sealed product should be discarded.

PRECAUTIONS

1. For in vitro diagnostic and forensic use only.
2. Do not use the product beyond the expiration date.
3. Handle all specimens as potentially infectious.
4. Humidity sensitive product, do not open foil pouch until it is ready to be tested.
5. Use a new urine specimen cup for each sample to avoid cross contamination.

SPECIMEN COLLECTION AND PREPARATION

Fresh urine does not require any special handling or pretreatment. A fresh urine sample can be collected in a clean, dry, plastic or glass container. If the urine specimen is collected in the container, it may be refrigerated at 2-8 °C or frozen up to 7 days prior to the testing. Specimens should be brought to room temperature before testing. Urine specimens exhibiting a large amount of precipitate or turbidity should be centrifuged or allowed to settle before testing. Avoid contact with skin by wearing gloves and proper laboratory attire.

QUALITY CONTROL

Good Laboratory practice recommends the daily use of control materials to validate the reliability of device. Control materials should be assayed as clinical specimen and challenging to the assay cutoff concentration, e.g., 50% above and below cutoff concentration. If control values do not fall within establish range, assay results are invalid. Control materials which is not provided with this test kit are commercially available.

The Rapid AMP Test provides a built-in process control with a different antigen/antibody reaction at the control region (C). This control line should always appear regardless the presence of drug. If the control line does not appear, the test device should be discarded and the obtained result is invalid. The presence of this control band in the control region serve as 1) verification that sufficient volume is added, 2) that proper flow is obtained.

PROCEDURE

For AMP Test Strip (Catalog Number: 1L01S3)

1. Bring test device and specimens to the room temperature (15-28ºC) if they have been refrigerated..
2. Remove the test strip from the sealed foil pouch and use it as soon as possible.
3. With arrows pointing toward the urine specimen, immerse the sample pad end of the test strip in the urine specimen..
4. Hold the test strip in a vertical position for at least 10 seconds.
5. Remove the test strip from the urine. While removing the test strip, run the edge of the strip against the rim of the specimen container to remove excess urine.
6. Place the test strip on a clean, dry and non-absorbent surface.
7. Read the results at 5 minutes after adding the sample.

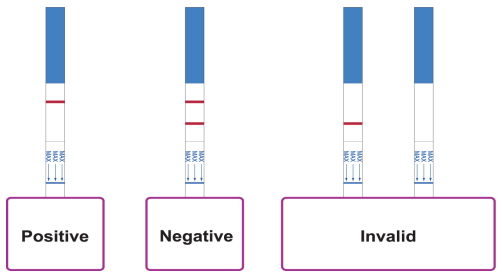
For AMP Test Card (Catalog Number: 1L01C3)

1. Bring all materials and specimens to room temperature.
2. Remove the test card from the sealed foil pouch.
3. Label the test card with specimen identity on the "ID ____ " area of the cassette.
4. Place the test card on a flat horizontal surface.
5. Using the transfer pipet to draw up the sample.
6. Hold the pipette in a vertical position over the sample well marked as "S" on the test card and drip 2-3 drops (80-120 μl) sample into the sample well.
7. Read the results at 5 minutes after adding the sample.

Note: Do not interpret the results after 10 minutes.

INTERPRETATION OF RESULTS

Test Strip:



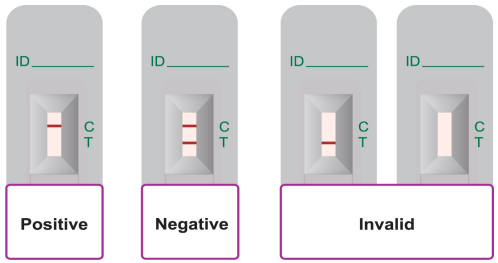
Negative:

Two colored bands form. The appearance of two colored bands, one in test line zone and the other in control line zone, indicates negative result for that particular test(s). The negative result does not indicate the absence of drug and their metabolites in the specimen, it only indicates the level of tested drug and their metabolites in the specimen is less than cut-off level.

Positive:

One colored band forms. One colored band appears in control line zone. No colored band is found in test line zone. This is an indication the level of tested drug and their metabolites in the specimen is above the cut-off level.

Test Card:



Invalid:
If there is no colored band in control line zone of any strip, the test result is invalid. Retest the sample with a new device.
Note: A borderline(±) in test line zone should be considered negative result.

LIMITATION OF PROCEDURE
The assay is designed for use with human urine only. A positive result with the test indicates only the presence of drug/metabolite and does not indicate or measure intoxication. There is a possibility that technical or procedural error as well other substances in certain foods and medicines may interfere with the test and cause false results. Please refer "SPECIFICITY" section for lists of substances that will produce either positive results, or that do not interfere with test performance. If drug/metabolite is found present in the urine specimen, the assay does not indicate frequency of drug use or distinguish between drug of abuse and certain foods and medicines.

EXPECTED RESULTS
The Rapid AMP Test is a qualitative assay. It identifies the drug in human urine at its cut-off concentration or higher. The concentration of the drug can not be determined by this assay. The test is intended to distinguish negative result from presumptive positive result. All positive results must be confirmed using an alternate method, preferably GC/MS.

PERFORMANCE CHARACTERISTICS
A. Accuracy
The accuracy of the amphetamine test was evaluated in comparison to GC/MS method and commercial kits at a cut-off of 1000 ng/ml. Three hundred and forty five (345) urine specimens which composed of one hundred thirty three (133) d-amphetamine positive samples and two hundred twelve (212) negative samples were evaluated in this study. The results are summarized and presented below:
Positive % agreement: 98.5, Negative % agreement: 100
B. Sensitivity
The cut-off concentration (sensitivity level) of the Rapid AMP Test is determined to be: AMP 1000 ng/ml.
C. Precision
The precision of Rapid AMP Test was determined by conducting the test with spiked controls and interpreted the results by three individuals to verify the random error of visual interpretation. The results of 40 samples each of 50% above and 50% below cut-off specimens are 100% agreed by three observers. The test results were found to have no significant differences between these three observers.
D. Specificity
The specificity for Rapid AMP Test was tested by adding various drugs, drug metabolites, and other compounds that are likely to be present in urine. All compounds were prepared in drug-free normal human urine.
1. Interference testing
The Rapid AMP Test performance at cut-off level is not affected when pH and Specific Gravity ranges of urine specimen are at 4.0 to 9.0 and 1.005 to 1.035.
The following substances were tested and confirmed did not interfere with Rapid AMP Test at the listed concentrations.

Glucose	2000 mg/dl,
Human albumin	2000 mg/dl
Human hemoglobin	10 mg/dl,
Urea	4000 mg/dl
Uric acid	10 mg/dl

2. Specificity
The following table lists compounds that may produce positive results when tested at levels equal or greater than the concentrations listed below:

Tests	Compounds	Cut-off (ng/ml)
Amphetamine	D-Amphetamine	1,000
	D/L-Amphetamine	2,000
	(±)-MDA	2,500
	L-Amphetamine	30,000
	Tyramine	50,000

The following compounds show no cross-reactivity at concentration up to100 ug/mL unless specified in the table above.

Acetamidophenol	Acetaminophen	6-Acetylmorphine	Acetylsalicyclic acid
Alfentanil HCL	Alprazolam	7-Aminoclonazepam	7-Aminoflunitrazepam
7-Aminonitrazepam	Amitriptyline Hydrochloride	Amobarbital Sodium	(±)Amphetamine
Ascorbic acid	Atenolol	Atropine	Benzoylecgonine
Bromazepam	Buprenorphine	Butalbital	Caffeine
Cannabidiol	Cannabinal	Chlordiazepoxide	Chloroquine
Chlorpheniramine	Cis-Tramadol	Citalopram HBr	Clobazam
Clonazepam	Cocaine Hydrochloride	Codeine	Cortisone
Cotinine	(-)-delta8-THC	(-)-delta9-THC	Desipramine
Dextromethorphan	Diazepam	Digitoxin	Digoxin
Dihydrocodeine	Diphenhydramine	Doxepin	Doxylamine succinate
d-Pseudoephedrine	EDDP Perchlorate	EMDP	Estazolam
Ethylmorphine	(-)Ephedrine Hydrochloride	Fentanyl	Flunitrazepam
Fluoxetine	Flurazepam	Gentisic acid	Guaiacol glycer ester
Heroin	Hydrochlorothiazine	Hydrocodone	Hydromorphone
(±)-11-Hydroxy-delta9-THC	Hydroxyzine	Ibuprofen	Imipramine Hydrochloride
Isoproterenol	Ketamine	Lidocaine	Lorazepam
Lormetazepam	(±)-MBDB	(±)-MDA	(±)MDEA
(±)-MDMA	Meperidine	(±)Methadone	(±)Methamphetamine
(+)-Methamphetamine	Methaqualone	Methylphenidate	Midazolam
Morphine	Morphine-3-β-glucuronide	Nalbuphine	Nalorphine
Naloxone	Natrexone	N-Desmethyl-cis tramadol	Neomycin
Niacianamide	Nitrazepam	Norbuprenorphine	(-)-11-nor-9-Carboxy-delta 9-THC
Norcodeine	Nordiazepam	(±)-Norketamine	Normorphine
Norpropoxyphene	Norsertraline	Nortriptyline	O-Desmethyl-cis tramadol
Orphenadine	Oxazepam	Oxcarbazepine	Oxycodone
Oxymorphone	Pentobarbital	Perphenazine	Phencyclidine (PCP)
Phenobarbital	β- Phenylethylamine	Phenylpropanolamine	Prazepam
Promethazine	Propoxyphene	(±)-Propranolol	Protriptyline
Quetiapine fumarate	R(-)-Epinephrine	R(-)-Methamphetamine	Ranitidine
Ritalinic acid	S(-)-Nicotine	Salicyclic acid	Secobarbital
Sertraline	Temazepam	Tetracycline	Tetrahydrozoline
Theophyline	Thioridazine	Triazolam	Trimipramine
Tyramine	Venlafaxine	Verapamil