

# Acro Rapid Methamphetamine Urine Test

Ref. No. 1018

## INTENDED USE

The Acro Rapid Methamphetamine Urine Test is a lateral flow, rapid immunoassay for the qualitative detection of methamphetamine in human urine at a cutoff of 500 ng/mL. This test is used to obtain a visual qualitative result and is intended for laboratory use only.

This assay provides only a preliminary result. Clinical consideration and professional judgment must be applied to a drug test result, particularly in evaluating a preliminary positive result. In order to obtain a confirmed analytical result, a more specific alternate chemical method is needed. Gas Chromatography/Mass Spectroscopy (GC/MS) analysis is preferred.

## SUMMARY AND EXPLANATION

Methamphetamine is a potent central nervous system stimulant. Acute high doses induce euphoria, alertness, and sense of increased energy and power. More acute responses produce anxiety, paranoia, psychotic behavior, and cardiac dysrhythmias. Methamphetamine is excreted in urine as amphetamine and oxidized as deaminated and hydroxylated derivatives. However, methamphetamine is also excreted to some extent unchanged. Thus, the presence of the parent compound in the urine indicates methamphetamine use.

The length of time following drug use for which a positive result may occur is dependent upon several factors, including the frequency and amount of drug, metabolic rate, excretion rate, drug half-life, the drug user's age, weight, activity and diet.

## TEST PRINCIPLE

The Acro Rapid Methamphetamine Urine Test is based on the principle of competitive immunochemical reaction between an immobilized drug-protein conjugate and the drug or drug metabolites, which may be present in the urine sample for limited binding sites of a labeled antibody. The test contains a nitrocellulose membrane strip pre-coated with drug-protein conjugate in the test region and a wicking pad containing colored antibody-colloidal gold conjugate. During the test, the urine sample is allowed to migrate upward and hydrate the antibody-colloidal gold conjugate. The mixture then migrates along the membrane chromatographically by capillary action to the immobilized drug-protein band in the test region. When drug is absent in the urine, the colored antibody-colloidal gold conjugate and immobilized drug-protein bind specifically to form a visible line in the test region (test line). When methamphetamine is present in the urine sample, it will compete with the drug-protein for the limited antibody binding sites. The test line will be less intense with increasing drug concentration. When the drug is present in sufficient concentration in the urine sample, it will fill the limited antibody binding sites, which will inhibit attachment of the colored antibody-colloidal gold conjugate to the drug-protein conjugate in the test region. Therefore the presence of the test line indicates a **negative** result for methamphetamine and the absence of the test line indicates a **preliminary positive** result for methamphetamine.

Another visible line, control line, generated by a different antigen/antibody reaction is also present at a control region (C) next to the test region of the test strip. The control line should always appear, regardless of the presence of the drug or drug metabolites in the urine sample. This means that a **negative** urine sample will produce **two** lines (test line and control line), and a **positive** urine sample will generate only **one** line (control line). The presence of control line serves as a built-in control, which demonstrates that sufficient volume was added.

## REAGENTS AND MATERIALS PROVIDED

1. Test Cassette contains membrane-embedded reagents in a protein matrix containing sodium azide as a preservative.
2. Anti-methamphetamine monoclonal antibody is from murine ascites.
3. Dropper. A transfer pipette is included with each test device inside the foil pouch.
4. Test Instructions

## MATERIALS REQUIRED, BUT NOT PROVIDED

1. Timer
2. Sample container

## WARNINGS AND PRECAUTIONS

1. For laboratory *in vitro* diagnostic use only
2. Urine specimens may be potentially infectious. Proper handling and disposal procedures should be followed.
3. Avoid cross-contamination of urine samples. Use a new dropper or transfer pipette for adding each test sample.
4. Test device should remain sealed until ready for use.
5. Do not use the test kit after the expiration date.

## STORAGE AND STABILITY

Store at 2-30°C (36-86°F) in the original sealed pouch. Do not freeze.

## SPECIMEN COLLECTION AND HANDLING

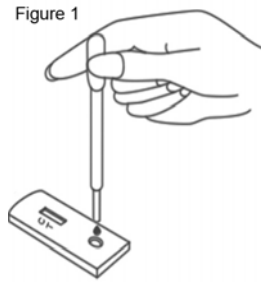
Fresh urine does not require any pretreatment. A fresh urine sample should be collected in the container provided. Alternatively, a clean dry plastic or glass container may be used for specimen collection. If the specimen is not immediately tested after the specimen collection, the specimen may be refrigerated at 2-8°C for up to 2 days or frozen at -20°C for longer period of time. Specimens that have been refrigerated must be equilibrated to room temperature prior to testing. Frozen specimens must be thawed and mixed thoroughly prior to testing.

Note: Urine specimens and all materials coming in contact with the specimens should be handled and disposed as if capable of transmitting infection. Avoid contact with skin by wearing gloves and proper laboratory attire.

## ASSAY PROCEDURE

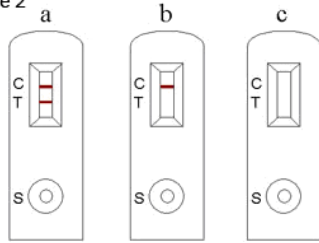
1. Bring the test components and urine sample to room temperature (15° - 28° C) before testing. Do not open the foil pouch until ready to begin testing.
2. Open the foil pouch at the notch and remove the test device and dropper prior to testing. Place the device on a clean, level surface.
3. Hold the dropper vertically and dispense 2 drops (~ 80 µl) of urine sample without air bubbles into the sample well "S" of the test device.
4. Read the result between 5 and 10 minutes.

**IMPORTANT:** Waiting more than ten minutes before reading the test result may cause the test result to be inaccurate.



## INTERPRETATION OF RESULTS

Figure 2



1. **Preliminary Positive:** a *rose-pink* color band appears in the Control Zone "C" but not in the Test Zone "T". A preliminary positive result indicates methamphetamine level in the urine sample is at or above the detection sensitivity of 500 ng/mL. The results should be confirmed.
2. **Negative:** two horizontal *rose-pink* color bands appear, one in the Control zone "C" and one in the Test Zone "T". A negative result indicates methamphetamine level is below the detection sensitivity of 500 ng/mL.
3. **Invalid:** no *rose-pink* bands appear, or a band appears in the Test Zone "T", but not in the Control Zone "C". An invalid result may be due to improper testing procedures or deterioration of the kit components.

**Note:** There is no meaning attributed to line color intensity or width.

## QUALITY CONTROL

An internal procedure control is included in the test device. A control line must form regardless of the presence or absence of drugs or metabolites. The presence of the line in the Control region indicates that a proper sample volume has been used. If the line in the Control region does not form, the test is considered invalid.

To ensure proper kit performance, it is recommended that the test devices be tested once a week or prior to use with external controls. External controls are available from commercial sources. It is important to make sure the results of the control materials are correct. If they are not the test results are invalid. Additional controls may be tested according to guidelines or requirement of local state, and/or federal regulations or accrediting organizations.

## LIMITATIONS OF PROCEDURE

1. The assay is designed for use with human urine only.
2. A preliminary positive result indicates only the presence of methamphetamine and does not indicate or measure intoxication
3. See specificity section for substances that have been shown to produce positive results, or that did not interfere with test performance under conditions described. There is a possibility that technical or procedural error as well as other substances not listed may interfere with the test and cause false results.
4. If adulteration is suspected, the test should be repeated with a new sample.
5. Some OTC or prescription drugs are known to interfere with methamphetamine assays.

## PERFORMANCE CHARACTERISTICS

1. **Analytical Sensitivity.** The Acro Rapid Methamphetamine Urine Test detects methamphetamine and its metabolites in urine at concentrations equal to or greater than 500 ng/mL. Please see the "cutoff study" and method comparison" section for details.
2. **Analytical Specificity.** Interference of substances that may be present in urine specimens, as well as effect of sample pH and specific gravity was also studied.
  - a. Cross-reactivity of non-methamphetamine related compounds were tested using the assay devices. No cross-reactivity was detected with the substances listed in Table I.
  - b. Table II lists Methamphetamine related substances and concentrations that produced results approximately equivalent to the cutoff level for methamphetamine.
  - c. Varying sample pH within the range of 4 and 9 has no significant effect on the assay results.
  - d. Varying sample specific gravity within the range of 1.003 and 1.040 has no significant effect on the assay results.

**Table-I: Compounds and concentrations tested and found not to interfere with the test.**

Acetaminophen (100 ug/mL)	Ibuprofen (200 ug/mL)
Acetone (100 ug/mL)	(+/-)-Isoproterenol (100 ug/mL)
Albumin (500 ug/mL)	Ketamine (100 ug/mL)

<i>Ampicillin</i> (100 ug/mL)	<i>Levorphanol</i> (100 ug/mL)
<i>Ascorbic Acid</i> (500 ug/mL)	<i>Lidocaine</i> (100 ug/mL)
<i>Aspartame</i> (100 ug/mL)	<i>(+)-Naproxen</i> (100 ug/mL)
<i>Aspirin</i> (100 ug/mL)	<i>Niacinamide</i> (100 ug/mL)
<i>Atropine</i> (100 ug/mL)	<i>Nicotine</i> (100 ug/mL)
<i>Benzocaine</i> (100 ug/mL)	<i>(+/-)-Norephedrine</i> (100 ug/mL)
<i>Bilirubin</i> (100 ug/mL)	<i>Oxalic Acid</i> (100 ug/mL)
<i>Caffeine</i> (100 ug/mL)	<i>Penicillin-G</i> (100 ug/mL)
<i>Chloroquine</i> (100 ug/mL)	<i>Pheniramine</i> (100 ug/mL)
<i>(+)-Chlorpheniramine</i> (100 ug/mL)	<i>Phenothiazine</i> (100 ug/mL)
<i>(+/-)-Chlorpheniramine</i> (100 ug/mL)	<i>1-Phenylephrine</i> (100 ug/mL)
<i>Creatine</i> (500 ug/mL)	<i>β-Phenylethylamine</i> (100 ug/mL)
<i>Dexbrompheniramine</i> (100 ug/mL)	<i>Procaine</i> (100 ug/mL)
<i>Dextromethorphan</i> (100 ug/mL)	<i>Quinidine</i> (100 ug/mL)
<i>Diphenhydramine</i> (100 ug/mL)	<i>Ranitidine</i> (100 ug/mL)
<i>Dopamine</i> (100 ug/mL)	<i>Riboflavin</i> (100 ug/mL)
<i>(+/-)-Epinephrine</i> (100 ug/mL)	<i>Sodium Chloride</i> (10,000ug/mL)
<i>Erythromycin</i> (100 ug/mL)	<i>Sulindac</i> (100 ug/mL)
<i>Ethanol</i> (0.2%)	<i>Theophylline</i> (100 ug/mL)
<i>Furosemide</i> (100 ug/mL)	<i>Tyramine</i> (100 ug/mL)
<i>Glucose</i> (500 ug/mL)	<i>4-Dimethylaminoantipyrine</i> (100 ug/mL)
<i>Guaiacol Glyceryl Ether</i> (100 ug/mL)	<i>(1R, 2S)-(-)-N-Methyl-Ephedrine</i> (100 ug/mL)
<i>Hemoglobin</i> (500 ug/mL)	

**Table-II: Methamphetamine-related compounds at the concentration indicated showed a positive response during testing of 1:1 serial dilutions.**

Compound /	Concentration in ng/ml
<i>d-Methamphetamine</i>	500
<i>d-Amphetamine</i>	50,000
<i>l-Amphetamine</i>	>100,000
<i>(+/-)3,4-MDEA</i>	50,000
<i>(+/-)3,4-MDA</i>	100,000
<i>(+/-)3,4-MDMA</i>	2,000
<i>l-Methamphetamine</i>	10,000
<i>Ephedrine</i>	100,000
<i>Mephentermine</i>	50,000
<i>Ranitidine</i>	600

**3. Method Comparison.** The accuracy study was performed by testing clinical methamphetamine urine samples with the device and comparing with a predicate rapid test or GC/MS analysis results. The negative samples were compared with the predicate device results, and 10% of the samples were confirmed with GC/MS analysis. All the positive samples were compared with GC/MS analysis results.

Acro Rapid MET Test	Negative (<50% cutoff by GC/MS or negative by predicate)	Near Cutoff Negative (50% - to cutoff)	Near Cutoff Positive (cutoff to 50%+ cutoff)	High Positive (>50%+ cutoff)
Positive	0	3	9	40
Negative	70	7	1	0

%agreement of the positives: 49/50 = 98%

%agreement of the negatives: 77/80 = 96%

**4. Reproducibility/Cut-off study.** The reproducibility of the assay at the cut-off and other concentrations was determined by the repetitive assaying of six levels of methamphetamine controls. The resultant data are summarized as follows:

Methamphetamine conc.	# Tested	# Positive (+)	# Negative (-)	% Correct Results
0 ng/mL	60	0	60	100%
250 ng/mL	60	0	60	100%
375 ng/mL	60	14	46	77%
625 ng/mL	60	44	16	73%
750 ng/mL	62	62	0	100%
1000 ng/mL	60	60	0	100%

## BIBLIOGRAPHY

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