

Rapid Urine MDMA Test
For *in vitro* diagnostic use only
MDMCS500

INTENDED USE

Acro Rapid MDMA Urine Test is a lateral flow, rapid immunoassay for the qualitative detection of 3,4-methylenedioxymethamphetamine (MDMA) in human urine at a cutoff of 500 ng/mL of MDMA. The 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

MDMA, most commonly known by the street name ecstasy or XTC, is a synthetic entactogen of the phenethylamine family whose primary effect is to stimulate the secretion of and inhibit the re-uptake of large amounts of serotonin as well as dopamine and norepinephrine in the brain, causing a general sense of openness, empathy, energy, euphoria, and well-being. Tactile sensations are enhanced for some users, making general physical contact with others more pleasurable; but, contrary to popular mythology it generally does not have aphrodisiac effects. Its ability to facilitate self-examination with reduced fear has proven useful in some therapeutic settings, leading to its 2001 approval by the United States FDA for testing in patients with post-traumatic stress disorder. Acute dehydration is a risk among users who are highly physically active and forget to drink water, as the drug may mask one's normal sense of exhaustion and thirst. Also the opposite, "water intoxication" resulting in acute hyponatremia has been reported. Sometimes more dangerous chemicals such as PMA or methamphetamine alone or in combination with MDMA are added to ecstasy tablets. Long-term effects in humans are largely unknown and the subject of much controversy – particularly with regard to the risks of severe long-term depression as a result of a reduction in the natural production of serotonin. MDA's psychological effect is generally similar to those of MDMA, including empathogen/entactogenic effects, though typically less intense than a similar dosage of MDMA. MDA is considered to be about 10x more neuro-toxic than its methylated cousin MDMA.

TEST PRINCIPLE

The Acro Rapid MDMA 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 for the drug/drug metabolites of a labeled drug antibody. The test device 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 MDMA is present in the urine sample, it will compete with the drug-protein conjugate for the limited antibody binding sites. 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 MDMA and the absence of the test line indicates a preliminary **positive** result for MDMA.

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 the test is performed properly.

REAGENTS & MATERIALS SUPPLIED

1. Test Cassette contains membrane-embedded reagents in a protein matrix containing sodium azide as a preservative.
2. Anti-MDMA 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.

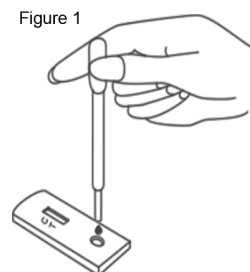
SPECIMEN COLLECTION AND HANDLING

Fresh urine does not require any special handling or pretreatment. 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 3 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.

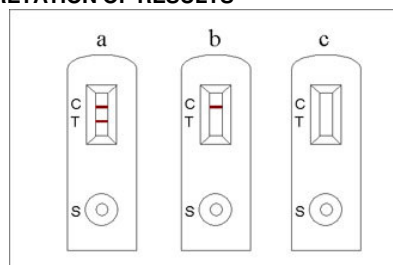
ASSAY PROCEDURE

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 5-10 minutes. A negative result may be read in less than 2 minutes. A preliminary positive result must be determined between 5-10 minutes.



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

INTERPRETATION OF RESULTS



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 MDMA level in the urine sample is at or above the detection sensitivity of 500 ng/mL. The sample 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 MDMA level in the urine sample 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 that the control values are within established limits. If the values of external controls do not fall within established limits, 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 MDMA and does not indicate or measure intoxication
3. There is a possibility that technical or procedural error as well as other substances as factors not listed may interfere with the test and cause false results. See SPECIFICITY section for substances that will produce positive results, or that do not interfere with the test performance.
4. If adulteration is suspected, the test should be repeated with a new sample.
5. Certain over the counter or prescription medications (or certain foods) may cause false results.

PERFORMANCE CHARACTERISTICS

1. **Sensitivity.** The Acro Rapid MDMA Urine Test detects MDMA and its metabolites in urine at concentrations equal to or greater than 1000 ng/mL.
2. **Specificity.** Interference of substances that may be present in urine specimens, as well as sample effect of sample pH and specificity were studied.
 - a. Cross-reactivity of non- MDMA related compounds at concentrations much higher than normally found in the urine of people using or abusing them were tested using the assay devices. No cross-reactivity was detected with the substances listed in Table I.
 - b. Table II lists MDMA related substances and concentrations that produced results approximately equivalent to the cutoff level for MDMA.
 - 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: The following drugs or food supplement substances were tested at concentrations higher than they normally would present in urine of people who use/abuse them and were found not to interfere with the test.

<i>Biotin</i>	<i>Zinc</i>
<i>Boron</i>	<i>Vitamin B6</i>
<i>Calcium chloride</i>	<i>Folic Acid</i>
<i>Chromium</i>	<i>Magnesium Hydroxide</i>
<i>Copper</i>	<i>L-Lysine</i>
<i>Iodine</i>	<i>Famotidine</i>
<i>Iron</i>	<i>Calcium Carbonate</i>
<i>Lutein</i>	<i>Citric Acid</i>
<i>Lycopene</i>	<i>Sodium Bicarbonate</i>
<i>Manganese</i>	<i>Aspirin</i>
<i>Molybdenum</i>	<i>Simethicone</i>
<i>Niacin</i>	<i>Loratadine</i>
<i>Nikel</i>	<i>Diphenhydramine HCl</i>
<i>Pantothenic Acid</i>	<i>Oxymetazoline HCl</i>
<i>phosphorus</i>	<i>Guafenesin</i>
<i>potassium</i>	<i>Dextromethorphan Hydrobromide</i>
<i>Selenium</i>	<i>Phenylephrine HCl</i>
<i>Silicon</i>	<i>Chlorpheniramine Maleate</i>
<i>Thiamin</i>	<i>Acetaminophen</i>
<i>Tin</i>	<i>Pseudoephedrine HCl</i>
<i>Vanadium</i>	<i>Doxylamine Succinate</i>
	<i>Naproxen Sodium</i>

<i>Vitamin A</i>	<i>Ibuprofen</i>
<i>Vitamin B12</i>	<i>Caffeine</i>
<i>Vitamin C</i>	<i>Dimenhydrinate</i>
<i>Vitamin D</i>	<i>Meclizine HCl</i>
<i>Vitamin E</i>	<i>Loperamide HCl</i>
<i>Vitamin K</i>	

Table-II: Concentration of MDMA-related compounds showing a positive response approximately equivalent to the MDMA cut-off set for the test.

Compound /	Concentration in ng/ml
<i>(+/-) 3,4-MDA</i>	500
<i>(+/-)-3,4-methylenedioxymethamphetamine (MDMA)</i>	500
<i>(+/-)-3,4-methylenedioxylethylamphetamine (MDEA)</i>	40
<i>d-Methamphetamine</i>	No cross-reaction when tested at 100ug/ml
<i>d-Amphetamine</i>	No cross-reaction when tested at 100ug/ml

3. **Cut-off Study.** The cut-off of the test was determined by the repetitive assaying of six levels of MDMA controls. The resultant data are summarized as follows:

MDMA conc.	# Tested	# Positive	# Negative	% Correct
		(+)	(-)	Results
0 ng/mL	60	0	60	100%
250 ng/mL	60	0	60	100%
375 ng/mL	60	12	48	80%
625 ng/mL	60	45	15	75%
750 ng/mL	60	60	0	100%
1000 ng/mL	60	60	0	100%

4. **Reproducibility.** The reproducibility was evaluated at four different sites. The Acro Rapid MDMA Urine Test was tested against blind-labeled urine controls containing 0, 250, 375, 625, 750 and 1000 ng/mL MDMA at each site. The results are summarized as follows:

Test Sites	0 ng/mL		250 ng/mL		375 ng/mL		625 ng/mL		750 ng/mL		1000 ng/mL	
	#	Result	#	Result	#	Result	#	Result	#	Result	#	Result
1	15	15-	15	15-	15	2+, 13-	15	11+, 4-	15	15+	15	15+
2	15	15-	15	15-	15	4+, 11-	15	11+, 4-	15	15+	15	15+
3	15	15-	15	15-	15	3+, 12-	15	11+, 4-	15	15+	15	15+
4	15	15-	15	15-	15	3+, 12-	15	12+, 3-	15	15+	15	15+
Total	60	60-	60	60-	60	12+, 48-	60	45+, 15-	60	60+	60	60+

5. **Stability Study.** As determined by temperature accelerated stability study method, the shelf life of the product under the specified storage condition is 24 months from the date of production.

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