MDMA Rapid Test Cassette (Urine)
Package Insert

REF DMD-102
English

A rapid test for the qualitative detection of Methylenedioxy-methamphetamine (MDMA) in human urine. For medical and other professional in vitro diagnostic use only.

INTENDED USE

The MDMA Rapid Test Cassette (Urine) is a rapid chromatographic immunoassay for the detection of Methylenedioxy-methamphetamine (primary ingredient of Ecstasy) in human urine at a cut-off concentration of 500 ng/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 confirmed analytical result. Gas chromatography/mass 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

Methylenedioxy-methamphetamine (Ecstasy) is a designer drug first synthesized in 1914 by a German drug company for the treatment of obesity.[1] Those who take the drug frequently report adverse effects, such as increased muscle tension and sweating. MDMA is not clearly a stimulant, although it has, in common with amphetamine drugs, a capacity to increase blood pressure and heart rate. MDMA does produce some perceptual changes in the form of increased sensitivity to light, difficulty in focusing, and blurred vision in some users. Its mechanism of action is thought to be via release of the neurotransmitter serotonin. MDMA may also release dopamine, although the general opinion is that this is a secondary effect of the drug (Nichols and Oberlender, 1990). The most pervasive effect of MDMA, occurring in virtually all people who have taken a reasonable dose of the drug, is to produce a clenching of the jaws. The MDMA Rapid Test Cassette (Urine) yields a positive result when Methylenedioxy-methamphetamine in urine exceeds 500 ng/mL.

PRINCIPLE

The MDMA Rapid Test Cassette (Urine) is an immunoassay based on the principle of competitive binding. Drugs which 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. Methylenedioxy-methamphetamine, if present in the urine specimen below 500 ng/mL, will not saturate the binding sites of antibody coated particles in the test. The antibody coated particles will then be captured by immobilized Methylenedioxy-methamphetamine 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 Methylenedioxy- methamphetamine level exceeds 500 ng/mL because it will saturate all the binding sites of anti-Methylenedioxy-methamphetamine antibodies.

A drug-positive urine specimen will not generate a colored line in the test line region, while a drug-negative urine 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 control line region indicating that proper volume of specimen has been added and membrane wicking has occurred.

REAGENTS

The test contains mouse monoclonal anti-Methylenedioxy-methamphetamine antibody-coupled particles and Methylenedioxy-methamphetamine-protein conjugate. A goat antibody is employed in the control line system.

PRECAUTIONS

- For medical and other professional *in vitro* diagnostic use only. Do not use after the expiration date.
- The test should remain in the sealed pouch until use.
- All specimens should be considered potentially hazardous and handled in the same manner as an infectious agent.
- The used test should be discarded according to local regulations.

STORAGE AND STABILITY

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

SPECIMEN COLLECTION AND PREPARATION

Urine Assay

The urine specimen must be collected in a clean and dry container. Urine collected at any time of the day may be used. Urine specimens exhibiting visible particles should be centrifuged, filtered, or allowed to settle to obtain a clear specimen for testing.

Specimen Storage

Urine specimens may be stored at 2-8°C for up to 48 hours prior to assay. For long-term storage, specimens may be frozen and stored below -20°C. Frozen specimens should be thawed and mixed before testing.

MATERIALS

Materials Provided

- Test cassettes
- Droppers
- Package insert

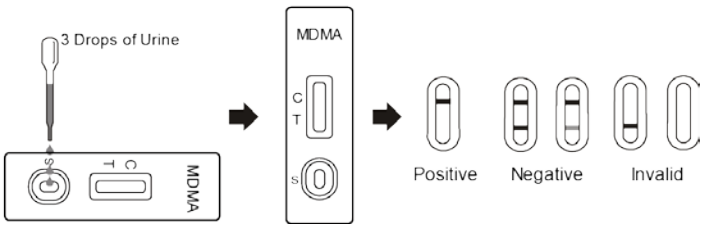
Materials Required But Not Provided

- Specimen collection containers
- Timer

DIRECTIONS FOR USE

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

1. Bring the pouch to room temperature 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 3 full drops of urine** (approx. 120µl) 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 color line(s) to appear. The result should be **read 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 control line region (C), and another apparent colored line should be in the test line region (T). This negative result indicates that the Methylenedioxy-methamphetamine concentration is below the detectable level (500 ng/mL).

***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 control line region (C). No line appears in the test line region (T). This positive result indicates that the Methylenedioxy-methamphetamine concentration exceeds the detectable level (500 ng/mL).

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

QUALITY CONTROL

A procedural control is included in the test. A colored line appearing in the control line region (C) is considered an internal procedural control. It confirms sufficient specimen volume, adequate membrane wicking and correct procedural technique.

Control standards are not supplied with this kit; however, it is recommended that positive and negative controls be tested as good laboratory practice to confirm the test procedure and to verify proper test performance.

LIMITATIONS

1. The MDMA Rapid Test Cassette (Urine) 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.[2,3]
2. It is possible that technical or procedural errors, as well as other interfering substances in the urine specimen may cause erroneous results.
3. Adulterants, such as bleach and/or alum, in urine specimens may produce erroneous results regardless of the analytical method used. If adulteration is suspected, the test should be repeated with another urine specimen.
4. A positive result indicates presence of the drug or its metabolites but does not indicate level of intoxication, administration route or concentration in urine.
5. A negative result may not necessarily indicate drug-free urine. Negative results can be obtained when drug is present but below the cut-off level of the test.
6. Test does not distinguish between drugs of abuse and certain medications.
7. A positive test result might be obtained from certain foods or food supplements.

EXPECTED VALUES

This negative result indicates that the Methylenedioxy-methamphetamine concentration is below the detectable level of 500ng/ml. Positive result means the concentration of Methylenedioxy-methamphetamine is above the level of 500ng/ml. The MDMA Rapid Test Cassette has a sensitivity of 500ng/ml.

PERFORMANCE CHARACTERISTICS

Accuracy

A side-by-side comparison was conducted using The MDMA Rapid Test Cassette and a commercially available MDMA rapid test. Testing was performed on 110 clinical specimens previously collected from subjects present for Drug Screen Testing. The following results were tabulated:

Method		Other MDMA Rapid Test		Total Results
MDMA Rapid Test Cassette	Results	Positive	Negative	
	Positive	48	0	48
	Negative	0	62	62
Total Results		48	62	110
% Agreement		>99.9%	>99.9%	>99.9%

A side-by-side comparison was conducted using The MDMA Rapid Test Cassette and GC/MS at the cut-off of 500ng/mL. Testing was performed on 250 clinical specimens previously collected from subjects present for Drug Screen Testing. The following results were tabulated:

Method		GC/MS		Total Results
MDMA Rapid Test Cassette	Results	Positive	Negative	
	Positive	102	1	103
	Negative	2	145	147
Total Results		104	146	250
% Agreement		98.1%	99.3%	98.8%

Analytical Sensitivity

A drug-free urine pool was spiked with Methylenedioxy-methamphetamine at the following concentrations: 0 ng/mL, 250 ng/mL, 375 ng/mL, 500 ng/mL, 625 ng/mL 750 ng/mL and 1,500 ng/mL. The result demonstrates >99% accuracy at 50% above and 50% below the cut-off concentration. The data are summarized below:

Methylenedioxy-methamphetamine Concentration (ng/mL)	Percent of Cut-off	n	Visual Result	
			Negative	Positive
0	0%	30	30	0
250	-50%	30	30	0
375	-25%	30	25	5
500	Cut-off	30	14	16
625	+25%	30	4	26
750	+50%	30	0	30
1,500	3X	30	0	30

Analytical Specificity

The following table lists compounds that are positively detected in urine by The MDMA Rapid Test Cassette (Urine) at 5 minutes.

Compound	Concentration (ng/mL)
(±) 3,4-Methylenedioxymethamphetamine HCl (MDMA)	500
(±) 3,4-Methylenedioxyamphetamine HCl (MDA)	3,000
3,4-Methylenedioxyethyl-amphetamine (MDE)	300

Precision

A study was conducted at three hospitals by laypersons 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 Methylenedioxy-methamphetamine, 25% Methylenedioxymethamphetamine above and below the cut-off and 50% Methylenedioxy-methamphetamine above and below the 500 ng/mL cut-off were provided to each site. The results are given below:

Methylenedioxy-methamphetamine Concentration (ng/mL)	n per Site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	10	10	0	10	0	10	0
250	10	10	0	10	0	10	0
375	10	8	2	9	1	9	1
625	10	1	9	1	9	1	9
750	10	0	10	0	10	0	10

Effect of Urinary Specific Gravity

Fifteen urine specimens of normal, high, and low specific gravity ranges were spiked with 250 ng/mL and 750 ng/mL of Methylenedioxy-methamphetamine. The MDMA Rapid Test Cassette (Urine) was tested in duplicate using the fifteen neat and spiked urine specimens. The results demonstrate that varying ranges of urinary specific gravity do not affect the test results.

Effect of Urinary pH

The pH of an aliquoted negative urine pool was adjusted to a pH range of 5 to 9 in 1 pH unit increments and spiked with Methylenedioxymethamphetamine to 250 ng/mL and 750 ng/mL. The spiked, pH-adjusted urine was tested with- The MDMA Rapid Test Cassette (Urine) in duplicate. The results demonstrate that varying ranges of pH do not interfere with the performance of the test.

Cross-Reactivity

A study was conducted to determine the cross-reactivity of the test with compounds in either drug-free urine or Methylenedioxy-methamphetamine positive urine. The following compounds show no cross-reactivity when tested with The MDMA Rapid Test Cassette (Urine) at a concentration of 100µg/mL.

Non Cross-Reacting Compounds

4-Acetamidophenol	Dextromethorphan	Meprobamate	Procaine
Acetophenetidin	Diclofenac	Methamphetamine	Promazine
N-Acetylprocainamide	Diazepam	Methadone	Promethazine
Acetylsalicylic acid	Diflunisal	Methoxyphenamine	D,L-Propranolol
Aminopyrine	Digoxin	Methylphenidate	D-Propoxyphene
Amitryptyline	Dicylomine	Morphine-	D-Pseudoephedrine
Amobarbital	Diphenhydramine	3-β-D-glucuronide	Quinacrine
Amoxicillin	5,5 - Diphenylhydantoin	Morphine sulfate	Quinidine

Ampicillin	Doxylamine	Nalidixic acid	Quinine
L-Ascorbic acid	Ecgonine hydrochloride	Naloxone	Ranitidine
D-Amphetamine	Ecgonine methylester	Naltrexone	Salicylic acid
D,L-Amphetamine sulfate	(-) -ψ-Ephedrine	Naproxen	Secobarbital
L-Amphetamine	[1R,2S](-) Ephedrine	Niacinamide	Serotonin
Apomorphine	L – Epinephrine	Nifedipine	(5-Hydroxytyramine)
Aspartame	Erythromycin	Nimesulidate	Sulfamethazine
Atropine	β-Estradiol	Norcodein	Sulindac
Benzilic acid	Estrone-3-sulfate	Norethindrone	Sustiva
Benzoic acid	Ethyl-p-aminobenzoate	D-Norpropoxyphene	Temazepam
Benzoylecgonine	Fenoprofen	Noscapine	Tetracycline
Benzphetamine	Furosemide	D,L-Octopamine	Tetrahydrocortisone,
Bilirubin	Gentisic acid	Oxalic acid	3- Acetate
(±) - Brompheniramine	Hemoglobin	Oxazepam	Tetrahydrocortisone
Buspiron	Hydralazine	Oxolinic acid	3-(β-D glucuronide)
Caffeine	Hydrochlorothiazide	Oxycodone	Tetrahydrozoline
Cannabidiol	Hydrocodone	Oxymetazoline	Thebaine
Cannabinol	Hydrocortisone	Papaverine	Theophynine
Chloralhydrate	O-Hydroxyhippuric acid	Penicillin-G	Thiamine
Chloramphenicol	p-Hydroxyamphetamine	Pentazocine	Trans-2-
Chlordiazepoxide	p-Hydroxy-	hydrochloride	phenylcyclopropylamine
Chlorothiazide	methamphetamine	Pentobarbital	Thioridazine
(±) - Chlorpheniramine	3-Hydroxytyramine	Perphenazine	Tolbutamide
Chlorpromazine	Imipramine	Phencyclidine	Trazodone
Chlorquine	Iproniazid	Phenelzine	D,L-Tyrosine
Cholesterol	(±) - Isoproterenol	Phenobarbital	Triamterene
Clomipramine	Isoxsuprine	Phentermine	Trifluoperazine
Clonidine	Ketamine	Trans-2-phenyl	Trimethoprim
Cocaethylene	Ketoprofen	cyclopropylamine	Trimipramine
Cocaine hydrochloride	Labetalol	hydrochloride	Tryptamine
Codeine	Levorphanol	L-Phenylephrine	D,L-Tryptophan
Cortisone	Loperamide	β-Phenylethylamine	Tyramine
(-) Cotinine	Maprotiline	Phenylpropanolamine	Uric acid
Creatinine	Meperidine	Prednisolone	Verapamil
Deoxycorticosterone	Mephentermine	Prednisone	Zomepirac

BIBLIOGRAPHY

1. Winger G. A Handbook of Drug and Alcohol Abuse. Third Edition, Oxford Press. 1992; 146
2. Baselt RC. Disposition of Toxic Drugs and Chemicals in Man. 2nd Ed. Biomedical Publ., Davis, CA. 1982; 488
3. Hawks RL, Chiang CN. *Urine Testing for Drugs of Abuse*. National Institute for Drug Abuse (NIDA), Research Monograph 73, 1986

	Attention, see instructions for use
	For in vitro diagnostic use only
	Store between 2-30°C
	Do not use if package is damaged
	Authorized Representative
	Catalog #
	Tests per kit
	Use by
	Lot Number
	Manufacturer
	Do not reuse
	Consult Instructions for Use

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Number: 145954500
Effective date: 2018-11-26