One Step
Ecstasy (MDMA) Test Device (Urine)
Package Insert

(Catalog Number: 1181-C)

BIOMERICA

A rapid, one step test for the qualitative detection of Methylenedioxymethamphetamine (MDMA) in human urine.

For in vitro diagnostic use only.

INTENDED USE

The MDMA One Step Ecstasy Test Device (Urine) is a lateral flow chromatographic immunoassay for the detection of Methylenedioxymethamphetamine (primary ingredient of Ecstasy) in human urine.

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

Methylenedioxymethamphetamine (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 One Step Ecstasy Test Device (Urine) yields a positive result when Methylenedioxymethamphetamine in urine exceeds 500 ng/mL.

PRINCIPLE

The MDMA One Step Ecstasy Test Device (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. Methylenedioxymethamphetamine, if present in the urine specimen below 500 ng/mL, will not saturate the binding sites of antibody coated particles in the test device. The antibody coated particles will then be captured by immobilized Methylenedioxymethamphetamine 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 Methylenedioxymethamphetamine level exceeds 500 ng/mL because it will saturate all the binding sites of anti-Methylenedioxymethamphetamine 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 device contains mouse monoclonal anti-Methylenedioxymethamphetamine antibody-coupled particles and Methylenedioxymethamphetamine-protein conjugate. A goat antibody is employed in the control line system.

PRECAUTIONS

- For *in vitro* diagnostic use only. Do not use after the expiration date.
- The test device 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 device should be discarded according to federal, state and local regulations.

STORAGE AND STABILITY

The kit can be stored at room temperature or refrigerated (2-30°C). The test device is stable through the expiration date printed on the sealed pouch. The test device 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 devices
- Disposable specimen droppers
- Package insert

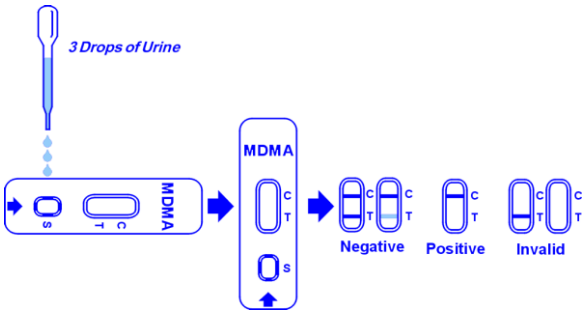
Materials Required But Not Provided

- Specimen collection container
- Timer
- External controls

DIRECTIONS FOR USE

Allow test device, 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 test device from the sealed pouch and use it as soon as possible.
2. Place the test device on a clean and level surface. Hold the dropper vertically and **transfer 3 full drops of urine** (approx. 100 µL) to the specimen well (S) of the test device, and then start the timer. Avoid trapping air bubbles in the specimen well (S). See illustration below.
3. Wait for the red 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 red line should be in the control region (C), and another apparent red or pink line should be in the test region (T). This negative result indicates that the Methylenedioxymethamphetamine concentration is below the detectable level (500 ng/mL).

***NOTE:** The shade of red in the test line region (T) may vary, but it should be considered negative whenever there is even a faint pink line.

POSITIVE: One red line appears in the control region (C). No line appears in the test region (T). This positive result indicates that the Methylenedioxymethamphetamine 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 device. 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 red line appearing in the control 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 One Step Ecstasy Test Device (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.

PERFORMANCE CHARACTERISTICS

Accuracy

A side-by-side comparison was conducted using the MDMA One Step Ecstasy Test Device (Urine) and a leading commercially available Methylenedioxymethamphetamine rapid test. Testing was performed on 240 clinical specimens. Ten percent of the specimens employed were either at -25% or +25% level of the cut-off concentration of 500 ng/mL Methylenedioxymethamphetamine. Presumptive positive results were confirmed by GC/MS. The following results were tabulated:

Method		Other MDMA Rapid Test		Total Results
One Step MDMA Test Device	Results	Positive	Negative	
	Positive	90	1	91
	Negative	0	149	149
Total Results		90	150	240
% Agreement with this Rapid Test Kit		100%	99%	99%

When compared at 500 ng/mL cut-off with GC/MS, the following results were tabulated:

Method		GC/MS				
		Negative	-25% Cut-off to Cut-off	Cut-off to +25% Cut-off	> +25% Cut-off	% agreement with GC/MS
MDMA Test Device	Positive	0	3	6	82	97
	Negative	147	2	0	0	100

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 and 750 ng/mL. The result demonstrates >99% accuracy at 50% above and 50% below the cut-off concentration. The data are summarized below:

MDMA 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	23	7
500	Cut-off	30	15	15
625	+25%	30	4	26
750	+50%	30	0	30

Analytical Specificity

The following table lists compounds that are positively detected in urine by the MDMA One Step Ecstasy Test Device (Urine) at 5 minutes.

Compound	Concentration (ng/mL)
(±) 3,4-Methylenedioxymethamphetamine HCl	500
(±) 3,4-Methylenedioxyamphetamine HCl	3,000
3,4-Methylenedioxyethylamphetamine	300

Precision

A study was conducted at 3 physicians' offices by untrained operators using 3 different lots of product to demonstrate the within run, between run and between operator precision. An identical panel of coded specimens containing no MDMA, 25% MDMA above and below the cut-off and 50% MDMA above and below the 500 ng/mL cut-off were provided to each site. The results are given below:

MDMA concentration (ng/mL)	n	Site A		Site B		Site C	
		-	+	-	+	-	+
0	15	15	0	15	0	15	0
250	15	15	0	15	0	15	0
375	15	10	5	11	4	11	4
625	15	2	13	2	13	0	15
750	15	0	15	0	15	0	15

Effect of Urinary Specific Gravity

Fifteen (15) urine specimens with specific gravity ranging from 1.001 to 1.032 were spiked with 250 ng/mL and 750 ng/mL of Methylenedioxymethamphetamine. The MDMA One Step Ecstasy Test Device (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 One Step Ecstasy Test Device (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 Methylenedioxymethamphetamine positive urine. The following compounds show no cross-reactivity when tested with the MDMA One Step Ecstasy Test Device (Urine) at a concentration of 100 µg/mL.

Non Cross-Reacting Compounds

4-Acetamidophenol
Acetophenetidin
N-Acetylprocainamide
Acetylsalicylic acid
Aminopyrine
Amitryptyline
Amobarbital
Amoxicillin
Ampicillin
L-Ascorbic acid
D-Amphetamine
DL-Amphetamine sulfate
L-Amphetamine
Apomorphine
Aspartame
Atropine
Benzilic acid
Benzoic acid
Benzoylecgonine
Benzphetamine
Bilirubin
(±) - Brompheniramine
Buspiron
Caffeine
Cannabidiol
Cannabinol
Chloralhydrate
Chloramphenicol
β-Estradiol
Estrone-3-sulfate
Ethyl-p-aminobenzoate
Fenoprofen
Furosemide
Gentisic acid
Hemoglobin
Hydralazine
Hydrochlorothiazide
Hydrocodone
Hydrocortisone
O-Hydroxyhippuric acid
p-Hydroxyamphetamine
p-Hydroxy-methamphetamine
3-Hydroxytyramine
Imipramine
Iproniazid
(±) - Isoproterenol
Isoxsuprine
Ketamine
Ketoprofen
Labetalol
Levorphanol
Loperamide
Maprotiline
Meperidine
Mephentermine
Pentobarbital
Perphenazine
Phencyclidine
Phenelzine
Phenobarbital
Phentermine
Trans-2-phenylcyclopropy-lamine hydrochloride
L-Phenylephrine
β-Phenylethylamine
Phenylpropanolamine
Prednisolone
Prednisone
Procaine
Promazine
Promethazine
DL-Propranolol
D-Propoxyphene
D-Pseudoephedrine
Quinacrine
Quinidine
Quinine
Ranitidine
Salicylic acid
Secobarbital
Serotonin (5-Hydroxytyramine)
Chlordiazepoxide
Chlorothiazide
(±) - Chlorpheniramine
Chlorpromazine
Chlorquine
Cholesterol
Clomipramine
Clonidine
Cocaethylene
Cocaine hydrochloride
Codeine
Cortisone
(-) Cotinine
Creatinine
Deoxycorticosterone
Dextromethorphan
Diclofenac
Diazepam
Diflunisal
Digoxin
Dicylomine
Diphenhydramine
5,5 - Diphenylhydantoin
Doxylamine
Ecgonine hydrochloride
Ecgonine methylester
(-) – ψ -Ephedrine
[1R,2S](-) Ephedrine
(L) - Epinephrine
Erythromycin
Meprobamate
Methamphetamine
Methadone
Methoxyphenamine
Methylphenidate
Morphine-3-β-D-glucuronide
Morphine sulfate
Nalidixic acid
Naloxone
Naltrexone
Naproxen
Niacinamide
Nifedipine
Nimesulidate
Norcodein
Norethindrone
D-Norpropoxyphene
Noscapine
D,L-Octopamine
Oxalic acid
Oxazepam
Oxolinic acid
Oxycodone
Oxymetazoline
Papaverine
Penicillin-G
Pentazocine-hydrochloride
Sulfamethazine
Sulindac
Sustiva
Temazepam
Tetracycline
Tetrahydrocortisone, 3-acetate
Tetrahydrocortisone 3-(β-D glucuronide)
Trans-2-phenylcyclopropylamine
Tetrahydrozoline
Thebaine
Theophynine
Thiamine
Thioridazine
Tolbutamide
Trazodone
DL-Tyrosine
Triamterene
Trifluoperazine
Trimethoprim
Trimipramine
Tryptamine
D L-Tryptophan
Tyramine
Uric acid
Verapamil
Zomepirac

BIBLIOGRAPHY

1. A Handbook of Drug and Alcohol Abuse, Gail Winger, Third Edition, Oxford Press, 1992, page 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

	Storage Temperature	EC REP	Authorized Representative
LOT	Lot Code		Caution, See Instructions
	Expiration	IVD	For in vitro diagnostic use
	Manufacturer	REF	Catalog No.

Biomerica, Inc.,
17571 Von Karman Avenue
Irvine, CA 92614 USA

2°C 30°C

EC REP

CE

according to IVDD 98/79/ EC
MDSS
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