

SureStep™ MDMA

One Step Ecstasy Test Device (Urine) Package Insert
English

A rapid, one step test for the qualitative detection of Methylenedioxyamphetamine (MDMA) in human urine.
For medical and other professional *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 Methylenedioxyamphetamine (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

Methylenedioxyamphetamine (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 Oberlander, 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 Methylenedioxyamphetamine 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. Methylenedioxyamphetamine, 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 Methylenedioxyamphetamine 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 Methylenedioxyamphetamine level exceeds 500 ng/mL because it will saturate all the binding sites of anti-Methylenedioxyamphetamine 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-Methylenedioxyamphetamine antibody-coupled particles and Methylenedioxyamphetamine-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

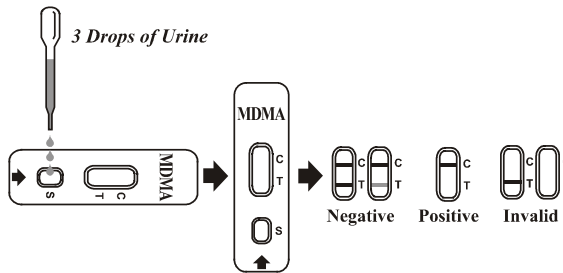
- Test devices
- Droppers
- Package insert

Materials Required But Not Provided

- Specimen collection container
- Timer

DIRECTIONS FOR USE

- Allow test, urine specimen, and/or controls to reach room temperature (15-30°C) prior to testing. Bring the pouch to room temperature before opening it. Remove the test device from the sealed pouch and use it as soon as possible.
- 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.
- Wait for the colored line(s) to appear. Read results 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 Methylenedioxyamphetamine 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 Methylenedioxyamphetamine 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

- 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}
- It is possible that technical or procedural errors, as well as other interfering substances in the urine specimen may cause erroneous results.
- 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.
- A positive result indicates presence of the drug or its metabolites but does not indicate level of intoxication, administration route or concentration in urine.
- 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.
- Test does not distinguish between drugs of abuse and certain medications.
- A positive test result might be obtained from certain foods or food supplements.

PERFORMANCE CHARACTERISTICS

Accuracy

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

Method	Other MDMA Rapid Test		Total Results
	Results	Positive	
MDMA One Step Test Device	Positive	90	91
	Negative	0	149
Total Results		90	150
% Agreement		>99%	99%

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

Method	GC/MS		Total Results
	Results	Positive	
MDMA One Step Test Device	Positive	88	91
	Negative	0	149
Total Results		88	152
% Agreement		>99%	98%

Analytical Sensitivity

A drug-free urine pool was spiked with Methylenedioxyamphetamine 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:

Methylenedioxyamphetamine 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	6	24
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-Methylenedioxyamphetamine HCl (MDMA)	500
(±) 3,4-Methylenedioxyamphetamine HCl (MDA)	3,000
3,4-Methylenedioxyethylamphetamine (MDE)	300

Precision

A study was conducted at three physicians' offices by untrained operators 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 Methylenedioxyamphetamine, 25% Methylenedioxyamphetamine above and below the cut-off and 50% Methylenedioxyamphetamine above and below the 500 ng/mL cut-off were provided to each site. The results are given below:

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

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 Methylenedioxyamphetamine. 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 Methylenedioxyamphetamine 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 Methylenedioxyamphetamine 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	Dextromethorphan	Meprobamate	Procaine
Acetophenetidin	Diclofenac	Methamphetamine	Propazine
N-Acetylprocainamide	Diazepam	Methadone	Propoxyphene
Acetylsalicylic acid	Diffenflinal	Methoxyphenamine	D,L-Propripranolol
Amipropirine	Digoxin	Methylphenidate	D-Propoxyphene
Amitypyline	Dicyclomine	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	Egonine hydrochloride	Naloxone	Ranitidine
D-Aspartamine	Egonine methylester	Naltrexone	Salicylic acid
D,L-Amphetamine sulfate	(-) - Ephedrine	Naproxen	Secobarbital
L-Amphetamine	[R-2S(+)] Ephedrine	Niacinamide	Serotonin
Aporphine	L - Ephedrine	Nitridipine	(S-Hydroxytryptamine)
Aspartame	Erythromycin	Nimesulide	Sulfamethazine
Atropine	β-Estradiol	Norecoidin	Sulindac
Benzilic acid	Estrone-3-sulfate	Norethindrone	Sustiva
Benzoic acid	Ethyl-p-aminobenzoate	D-Norpropoxyphene	Temazepam
Benzoylecgonine	Fenoprofen	Noscapine	Tetracycline
Fenzphetamine	Furosemide	D,L-Octopamine	Tetrahydrocortisone,
Bilirubin	Gentisic acid	Oxalic acid	3-Acetate
(±) - Brompheniramine	Hemoglobin	Oxazepam	Tetrahydrocortisone
Bupropion	Hydralazine	Oxoline acid	3-(β-D-glucuronide)
Caffeine	Hydrochlorothiazide	Oxycodone	Tetrahydrozoline
Cannabidiol	Hydrocodone	Oxymetazoline	Thebaine
Cannabinol	Hydrocortisone	Papaverine	Theophylline
Chloralhydrate	O-Hydroxyhippuric acid	Penicillin-G	Thiamine
Chloramphenicol	p-Hydroxyamphetamine	Pentazocine	Trans-2-
Chlordiazepoxide	p-Hydroxy-methamphetamine	hydrochloride	phenylecpropylamine
Chlorothiazide	3-Hydroxyamphetamine	Peribartal	Thioridazine
(±) - Chlorpheniramine	3-Hydroxyamphetamine	Perphenazine	Tolbutamide
Chlortriproprazine	Imipramine	Phenacemide	Trazodone
Chlorquine	Ipromidaz	Phenelzine	D,L-Tyrosine
Cholesterol	(±) - Isoproterenol	Phenobarbital	Triamterene
Clomipramine	Isosuxprine	Phentermine	Trifluoperazine
Clonidine	Ketamine	Trans-2-phenyl	Trimethoprim
Coacethylene	Ketoprofen	hydrocpropylamine	Trimipramine
Cocaine hydrochloride	Labetalol	hydrochloride	Tryptamine
Cocaine	Levorphanol	L-Phenylephrine	D,L-Tryptophan
Cortisone	Loperamide	β-Nephthylamine	Tyramine
(-) Cotinine	Maprotiline	Phenylpropanolamine	Uric acid
Creatinine	Meperidine	Prednisolone	Verapamil
Deoxycorticosterone	Mephentermine	Prednisone	Zomepirac

BIBLIOGRAPHY

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

Index of Symbols

	Attention, see instructions for use		Tests per kit		Authorized Representative
	For <i>in vitro</i> diagnostic use only		Use by		Do not reuse
	Store between 2-30°C		Lot Number		Catalog #



Innovacon, Inc.
4106 Sorrento Valley Boulevard
San Diego, CA 92121, USA



EC REP
MDSS GmbH
Schiffgraben 41
30175 Hannover, Germany

Number: 1155832401
Effective date: 2006-xx-xx