MDMA(Ecstasy) Test DipCard
Package Insert

Package insert for testing of any combination of the following drugs: MDMA(Ecstasy)

A rapid, screening test for thequalitative detection of MDMA(Ecstasy) in human urine.

For in vitro diagnostic use only.

INTENDED USE

MDMA(Ecstasy) Test is an immunoassay for the qualitative determination of MDMA(Ecstasy) in human urine at a Cut-Off concentration of 500ng/m L. The test is available in a DipCard format, a Cassette format, a Dip Card format and a Cup format.

The test may yield preliminary positive results even when prescription drug MDMA(Ecstasy) is ingested, at prescribed doses; it is not intended to distinguish between prescription use or abuse of this drug. There is no uniformly recognized cutoff concentration level for MDMA(Ecstasy) in urine. The test provides only preliminary test results. A more specific alternative chemical method must be used in order to obtain a confirmed analytical result. GC/MS is the preferred confirmatory method. Clinical consideration and professional judgment should be exercised with any drug of abuse test result, particularly when the preliminary result is positive.

For in vitro diagnostic use only.

SUMMARY

The **MDMA(Ecstasy) Test DipCard** is an immunoassay.

During testing, a urine sample migrates upward on the test DipCard. A drug-positive urine sample will not generate a colored line in the test line region, while a drug-negative urine sample or a sample containing a drug concentration less than the cut-off will generate a line in the test line region. A colored line will always appear at the control line region, indicating that proper volume of sample has been added.

PRECAUTIONS

- For *in vitro* diagnostic use only.
- Do not use after the expiration date.
- The Test DipCard should remain in the sealed pouch until use.

STORAGE AND STABILITY

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

SAMPLECOLLECTION AND PREPARATION

Urine Assay

The urine sample must be collected in a clean and dry container. Urine collected at any time of the day may be used.

MATERIALS

Materials Provided

• Test DipCard • Package insert

Materials also included:

1. Labeled Vials for shipping "preliminary" sample to the laboratory for confirmation
2. Plastic transportation bags
3. Mailing boxes
4. Personal identification numbers

DIRECTIONS FOR USE

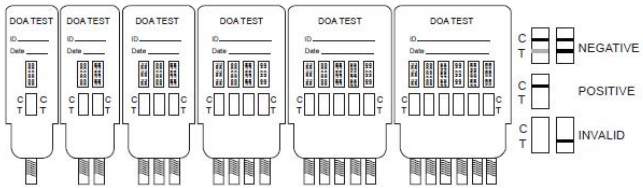
If refrigerated, allow the test device to come to room temperature [15-30°C (59-86°F)] prior to testing.

1) Remove the DipCard from the foil wrapper.

2) Fill a specimen cup (not provided) with fresh urine. Dip the DipCard into the urine with the arrow end pointing toward the urine. Do not cover the urineover the MAX (maximum) line. You may leave the DipCard in the urine or you may take the DipCard out after aminimum of 10-15 seconds in the urine and lay the DipCard flatly on a non-absorptive clean surface.

3) Read results at 5 minutes and do not throw away the urine. Urine used may be needed for confirmation testing. Please see the Results Interpretation and Mailing a Urine Sample sections of this labeling.

DO NOT INTERPRET RESULT AFTER 5 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 adjacent should be in the test region (Drug/T). This negative result indicates that the drug concentration is below the detectable level.

*NOTE: The shade of red in the test line region (Drug/T) will 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 (Drug/T). This positive result indicates that the drug concentration is above the detectable level.

INVALID: Control line fails to appear. Insufficient sample volume or not conducting the test as instructed 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, contact us.

A preliminary positive test result does not always mean a person took illegal drugs and a negative test result does not always mean a person did not take illegal drugs. There are a number of factors that influence the reliability of drug tests. Certain drugs of abuse tests are more accurate than others.

IMPORTANT: The result you obtained is called preliminary for a reason. The sample must be tested by laboratory in order to determine if a drug of abuse is actually present. Please refer to the Mailing a Urine Sample section of this labeling.

What Is A False Positive Test?

The definition of a false positive test would be an instance where the MDMA(Ecstasy) Urine Test is positive even though MDMA(Ecstasy) is not in the sample. The most common causes of a false positive test are cross reactants. Certain foods and medicines, diet plan drugs and nutritional supplements may also cause a false positive test result with this product.

What Is A False Negative Test?

The definition of a false negative test is that the initial MDMA(Ecstasy) is present but isn't detected by MDMA(Ecstasy) Urine Test. If the sample is diluted, or the sample is contaminated that may cause a false negative result.

LIMITATIONS

1. The **MDMA(Ecstasy) Test DipCard** 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. There is a possibility that interfering substances in the urine sample may cause erroneous results.
3. Substances, such as bleach and/or alum, in urine samples may produce erroneous results regardless of the analytical method used.
4. A positive result 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. The test does not distinguish between drugs of abuse and certain medications.
7. A positive result might be obtained from certain foods or food supplements.

QUESTIONS AND ANSWERS

1. What does the Drug of Abuse Urine Test do?

These tests indicate if one or more prescription or illegal drugs are present in urine. The testing is done in two steps. First, you do a quick at-home test. Second, if the test suggests that drugs may be present, you send the sample to a laboratory for additional testing.

2. What is "cut-off level"?

The cut-off level is the specified concentration of a drug in a urine sample. Above that concentration the test is called positive, and below that concentration it is called negative.

3. What are drugs of abuse?

Drugs of abuse are illegal or prescription medicines (for example, Oxycodone or Valium) that are taken for a non-medical purpose, including taking the medication for longer than your doctor prescribed it for or for a purpose other than what the doctor prescribed it for.

4. How accurate is the test?

The tests are sensitive to the presence of drugs in urine sample. These tests are not as accurate as lab tests. In some cases, certain foods and drugs may cause false positives as well as false negatives for those who use drug-testing kits..

5. Does a preliminary positive screen test mean that you have found of abuse?

This means that the test has reacted with something in the sample and the sample must be sent to the lab for a more accurate test.

6. What should I do, if the lab test confirms a positive result?

If you have received a confirmed positive result, please consult with our staff on a proper course of action. We will help you identify counselors who can help you. It is important that you remain calm and do not react in a negative way to the situation. If you do not believe the test result, please consult with your physician. They will have your background medical history and be able to provide you with detailed information on both the test and the meaning of the result.

MAILING A URINE SAMPLE TO THE LABORATORY FOR CONFIRMATION TESTING

1. Pour urine from the cup into the Labeled Vial. Ensure that the Labeled Vial is about two thirds (2/3) full with the urine that gave preliminary positive result(s) and that the cap is tightly closed. Only the urine that gave preliminary positive result(s) should be used for confirmation testing.
2. Please identify on the label, the drug that gave a preliminary positive result.
3. Be sure to write your Cell Phone Number on the mailing box so that the laboratory can send you a message with the confirmed results. The laboratory will also send you a Personal Identification Number.
4. Place the Labeled Vial in the plastic bag and seal the plastic bag.
5. Place the sealed plastic bag in the mailing box. Close the mailing box and secure it with packing tape. The mailing address for the laboratory is already on the mailing box. ***Please note that the mailing box isn't pre-paid. You must attach the proper postage to have a carrier service deliver it.***
6. Place the mailing box in any US Postal Service Office.

ASSISTANCE

If you have any question regarding to the use of this product, please call our Technical Support Number 1-866-982-3818 (9:00 a.m. to 5 p.m. CDT).

QUALITY CONTROL

If you work in a laboratory, you should perform quality control testing and you should read this section.

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 sample 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.Quality control testing should be performed with each new lot, each new shipment and every thirty days to check storage. Please contact our Technical Support at 1-866-982-3818 for controls that work with the device.

PERFORMANCE CHARACTERISTICS

Accuracy

80 clinical urine samples were analyzed by GC-MS and by the MDMA(Ecstasy) Test DipCard. Each test was performed by three operators. Samples were divided by concentration into five categories: drug-free, less than half the cutoff, near cutoff negative, near cutoff positive, and high positive. Results were as follows:

Test		Drug-free	Low Negative (Less than half the cutoff concentration)	Near Cutoff Negative (Between 50% below the cutoff and the cutoff concentration)	Near Cutoff Positive (Between the cutoff and 50% above the cutoff concentration)	High Positive (greater than 50% above the cutoff concentration)
Operator A	Positive	0	0	0	14	24
	Negative	10	15	15	2	0
Operator B	Positive	0	0	0	15	24
	Negative	10	15	15	1	0
Operator C	Positive	0	0	0	13	24
	Negative	10	15	15	3	0

% agreement among positives is 95%

% agreement among negatives is 100%

ANALYTICAL SENSITIVITY

Total 150 samples equally distributed at concentrations of -50% Cut-Off; -25% Cut-Off; Cut-Off; +25% Cut-Off; +50% Cut-Off were tested using three different lots of each device by three different operators. Results were all positive at and above +25% Cut-off and all negative at and below -25% Cut-off for MDMA(Ecstasy). The cut-off value 500ng/mL for the device is verified

ANALYTICAL SPECIFICITY

The following table lists compounds that are positively detected in urine by the MDMA(Ecstasy) Test DipCard Device.

Drug	Concentration (ng/ml)	% Cross-Reactivity
D,L-3,4-Methylenedioxymethamphetamine (MDMA)	500	100%
3,4-Methylenedioxyamphetamine HCl (MDA)	3,000	17%
3,4-Methylenedioxyethyla-amphetamine (MDEA)	300	167%
Labetalol	50,000	1%

PRECISION

This study is performed 2 runs/day and lasts 25 days for each format with three lots.Three operators who don't know the sample number system participate in the study. Each of the 3 operators tests 2 aliquots at each concentration for each lot per day (2 runs/day). A total of 50 determinations by each operator, at each concentration, were made. The results are given below:

MDMA(Ecstasy) concentration (ng/mL)	n	Lot1		Lot2		Lot3	
		-	+	-	+	-	+
0	50	50	0	50	0	50	0
125	50	50	0	50	0	50	0
250	50	50	0	50	0	50	0
375	50	50	0	50	0	50	0
500	50	24	26	24	26	24	26
625	50	0	50	0	50	0	50
750	50	0	50	0	50	0	50
875	50	0	50	0	50	0	50
1000	50	0	50	0	50	0	50

Effect of Urinary Specific Gravity

Fifteen (15) urine samples of normal, high, and low specific gravity from 1.000 to 1.035 were spiked with drugs at 25% below and 25% above cut-off levels respectively. The **MDMA(Ecstasy) Test DipCard** was tested in duplicate using ten drug-free urine and spiked urine samples. The results demonstrate that varying ranges of urinary specific gravity do not affect the test results.

Effect of Urinary pH

The pH of an aliquot of negative urine pool is adjusted in the range of 4.00 to 9.00 in 1 pH unit increment and spiked with the target drug at 25% below and 25% above Cutoff levels. The spiked, pH-adjusted urine was tested with The **MDMA(Ecstasy) Test DipCard**. 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 MDMA(Ecstasy), positive urine. The following compounds show no cross-reactivity when tested with the **MDMA(Ecstasy) Test DipCard** at a concentration of 100 µg/mL.

Non Cross-Reacting Compounds

Acetophenetidin	Creatinine	Meprobamate	Promethazine
N-Acetylprocainamide	Deoxyepinephrine	Methadone	Propoxyphene,d-
Acetylsalicylic Acid (Aspirin)	Dextromethorphan	Methoxyphenamine	Propranolol
Aminopyrine	Diazepam	Methylphenidate	Pseudoephedrine HCL
Amitriptyline	Diflunisal	Nalbuphine	Quinidine
Amoxicillin	Digoxin	Nalidixic acid	Quinine
Amobarbital	Doxylamine	Naloxone hydrochloride	Ranitidine(Zantac)
D-Amphetamine	Ecgonine methylester	Naltrexone hydrochloride	Salicylic Acid
L-Amphetamine	R(-)-Epinephrine	Naproxen	Secobarbital
Amphetamine Sulfate	Erythromycin	Niacinamide	Serotonin
Ampicinine(Ampicillin)	Estrone-3-sulfate	Nifedipine	Sulfamethazine
Apomorphine	Ethyl Morphine	Norethindrone	Sulindac
L-Ascorbic Acid	Ethyl-p-aminobenzoate	Norpropoxyphene	Temazepam
Aspartame	Fenoprofen	Noscapine	11-Nor-Δ^9-Tetrahydrocannabinol
Atropine	Furosemide	Oxazepam	Tetracycline
Benzilic acid	Gentisic acid	Oxycodone	Tetrahydrozoline
Benzphetamine	Hemoglobin	Oxymetazoline	Thebaine
Bezoic Acid	Hydralazine	Papaverine	Thiamine
Bilirubin	(+/-)-4-Hydroxyamphetamine HCL	Penicillin	L-Thyroxine
Caffeine	Hydrochlorothiazide	Pentobarbital	ThioridazineHydrochloride
Chloramphenicol	Hydrocodone	Perphenazine	Triamterene
Chlordiazepoxide HCL	Hydrocortisone	Phencyclidine	Trifluprom azine Hydrochloride
Chloroquine	a -Hydroxyhippuric acid	Phenelzine	Trimethoprim
Chlorothiazide	p-Hydroxymethamphetamine	Phenobarbital	Trimipramine
Chlorpheniramine	Ibuprofen	Phentermine	Tryptamine
Chlorpromazine	Imipramine	Phenylephrine-L	DL-Tryptophan
Cholesterol	Isoxsuprine	Phenylethylamine	Tyramine
Clomipramine	Isoproterenol-(+/-)	Phenylpropanolamine	D/L-Tyrosine
Clonidine hydrochloride	Ketamine	Prednisolone Acetate	Uric Acid
Codeine	Levorphanol	Prednisone	Verapamil
Cortisone	Loperamide	Procaine(Novocaine)	Zomepirac
Cotinine(-)	Maprotiline	Promazine	

Lay User Study

A lay user study was performed at three intended user sites with 140 lay persons. For a DipCard device study, participants were 54 females and 86 males tested the MDMA(Ecstasy) sample. They had diverse educational and professional backgrounds and ranged in age from 21 to >50. Urine samples were prepared at the following concentrations; negative, +/-75%, +/-50%, +/-25% of the cutoff by spiking drug(s) into drug free-pooled urine samples. The concentrations of the samples were confirmed by GC/MS. Each sample was aliquoted into individual containers and blind-labeled. Each participant was provided with the package insert, 1 blind labeled sample and a device. The typical results are summarized below.

% of Cutoff	Number of samples	MDMA(Ecstasy) Concentration by GC/MS (ng/mL)	Lay person results		The percentage agreement (%)
			No. of Positive	No. of Negative	
-100%Cutoff	20	0	0	20	100%
-75%Cutoff	20	125	0	20	100%
-50% Cutoff	20	250	0	20	100%
-25% Cutoff	20	375	1	19	95%
+25% Cutoff	20	625	19	1	95%
+50% Cutoff	20	750	20	0	100%
+75% Cutoff	20	875	20	0	100%

BIBLIOGRAPHY

1. Stewart DJ, Inaba T, Lucassen M, Kalow W. Clin. Pharmacol. Ther. April 1979; 25 ed: 464, 264-8.
2. Ambre J. J. Anal. Toxicol. 1985; 9:241.
3. Hawks RL, CN Chiang. Urine Testing for Drugs of Abuse. National Institute for Drug Abuse (NIDA), ResearchMonograph 73, 1986.
4. Tietz NW. Textbook of Clinical Chemistry. W.B. Saunders Company. 1986; 1735.
5. FDA Guidance Document: Guidance for Premarket Submission for Kits for Screening Drugs of Abuse to beUsed by the Consumer, 1997.

ADDITIONAL INFORMATION AND RESOURCES

The following list of organizations may be helpful to you for counseling support and resources. These groups also have an Internet address which can be accessed for additional information.

National Clearinghouse for Alcohol and Drug Information www.health.org 1-800729-6686

Center for Substance Abuse Treatment www.health.org 1-800-662-HELP

The National Council on Alcoholism and Drug Dependence www.ncadd.org 1-800-NCA-CALL

American Council for Drug Education (ACDE) www.acde.org 1-800-488-DRUG

INDEX OF SYMBOLS


Keep away from sunlight

Store between 2°C and 30°C


Keep dry


Do not re-use