

INSTANT-VIEW[®] MDMA (XTC) Urine Dip-Strip Test



One Step Assay
Rapid Visual Results
For Qualitative In Vitro Diagnostic Use

INTENDED USE

This device is a one-step immunoassay intended to provide qualitative rapid detection of methylenedioxymethamphetamine (MDMA, or Ecstasy, XTC) in human urine at a cut-off concentration of 500ng/ml. It is for health care professional use only.

This assay provides only a preliminary 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 obtained.

SUMMARY AND EXPLANATION OF THE TEST

MDMA is an abbreviation of the chemical methylenedioxymethamphetamine. It also has the street names Ecstasy, X, XTC, E, Love Doves, Clarity, Adam, Disco Biscuits, and Shamrocks. MDMA is a stimulant with hallucinogenic tendencies. It is described as an empathogen since it releases mood-altering chemicals, such as cartoning and L-dopa, in the brain and may generate feelings of love and friendliness. MDMA is a Class A drug, in the same category as heroin and cocaine. The adverse effects of MDMA use include elevated blood pressure, hyperthermia, anxiety, paranoia, and insomnia. Overdoses of MDMA can be fatal, often resulting in heart failure or heat stroke.

MDMA belongs to a "family" of man-made drugs; its "relatives" are MDA (methylenedioxyamphetamine), the parent drug of MDMA, and MDEA (methylenedioxyethylamphetamine), also known as EVE, the sister of MDMA. They all have the amphetamine-like effects. MDMA is administered either by oral ingestion or intravenous injection. MDMA tablets come in different sizes and colors, and often have logos such as doves on them. Its clinical dose is 50-100mg; the threshold toxic dose is 500mg. The effects of the MDMA begin 30 minutes after taking. They peak in an hour and last for 2-3 hours. Sixty five percent (65%) of MDMA is excreted unchanged in urine and it is detectable in the urine for up to 3 days after use.

PRINCIPLE OF THE PROCEDURE

This assay is a one-step lateral flow chromatographic immunoassay. The test strip includes: 1) a burgundy colored conjugate pad containing mouse anti-MDMA antibody coupled to colloidal gold; and 2) nitrocellulose membrane containing a Test (T) line and a Control (C) line. The Test line is coated with MDMA-BSA, and the Control line is coated with goat anti-rabbit IgG antibody.

This test is a competitive binding immunoassay. The MDMA in the urine specimen competes with the MDMA-BSA antigen coated on the nitrocellulose membrane for the limited binding sites of the conjugate anti-MDMA antibodies.

When an adequate amount of urine specimen is applied onto the sample pad of the device, the urine specimen migrates by capillary action through the test strip. If the level of MDMA in the urine specimen is below the cutoff (500 ng/ml), the Test line should appear as a visible burgundy line. If the level of MDMA in the urine specimen is at or above the cutoff, no Test line develops.

The C line binds to the gold-conjugated rabbit IgG and forms a burgundy colored line, regardless of the presence of MDMA.

REAGENTS AND MATERIALS SUPPLIED

- 50 test devices, each sealed in a pouch with a desiccant.
- 1 package insert (Instructions for Use).

MATERIAL REQUIRED BUT NOT PROVIDED

- Specimen collection containers
- Timer

STORAGE AND STABILITY

Store the kit at room temperature 15-30°C (59-86°F). Each device may be used until the expiration date printed on the label if it remains sealed in its foil pouch containing desiccant.

Do not freeze and/or expose the kit to temperatures over 30°C (86°F).



SPECIMEN COLLECTION

1. Each urine specimen must be collected in a clean container. Do not mix specimens.
2. Specimens may be kept at 15-30°C (59-86°F) for 8 hours, at 2-8°C for up to 3 days and at -20°C or lower for long term storage.

33-2957 REV H 020609

PRECAUTION

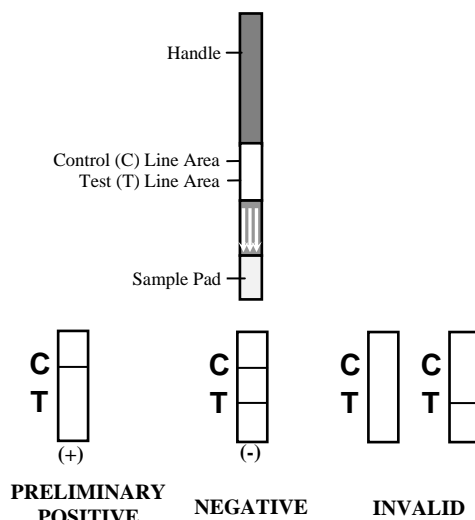
1. The instructions must be followed exactly to obtain accurate results.
2. Do not open the sealed pouch, unless ready to conduct the assay.
3. Do not use expired devices.
4. Dispose of all specimens and used assay materials as potentially biohazardous.

ASSAY PROCEDURE

1. Refrigerated specimens and other test materials, including devices, **must be equilibrated to room temperature before testing.**
2. Open the foil pouch at the notch and remove the test device.
3. Dip the device in the specimen for at least 10 seconds. Keep the specimen surface at the level indicated by the arrow sign on the device.
4. Remove the device from the specimen, and place it on a flat, dry surface.
5. Read the test result between four (4) to seven (7) minutes after adding the specimen.

INTERPRETATION OF RESULTS

IMPORTANT: Do not read test results after seven (7) minutes. The T Line should always be interpreted independently of the C Line.



Positive:

If only the C line appears, the test indicates that the MDMA level in the sample is at a cutoff of 500 ng/ml or higher.

Samples with preliminary positive results should be confirmed with a more specific method before a positive conclusion is made.

Negative:

If both C line and T line appear, the test indicates that the MDMA level is below 500 ng/ml.

Note: A faint T line should be considered negative.

Invalid:

If no C line develops within 5 minutes, repeat the assay with a new test device.

QUALITY CONTROL

Built-in Control Features

This test contains a built-in control feature, the C line. The presence of the C line indicates that an adequate volume of sample was used and that the reagents migrated properly. If a C line does not form, the test is considered invalid. In this case, review the whole procedure and repeat the test with a new device.

External Quality Control

Users should always follow the appropriate federal, state, and local guidelines concerning the running of external quality controls. SAMHSA recommends that the concentration of drug(s) in positive and negative controls be approximately 25% above and below the cutoff concentration of the assay.

LIMITATIONS

1. This test is for *professional in vitro* diagnostic use only.
2. There is a possibility that other substances and/or factors not listed in this instruction may interfere with the test and cause false results, e.g., technical or procedural errors.
3. Some adulterants such as bleach or other strong oxidizing agents may produce erroneous test results if added in the device. When suspected, collect a fresh specimen and repeat the test with a new device.

INSTANT-VIEW[®] MDMA (XTC) Urine Dip-Strip Test



EXPECTED VALUES

This test is capable of detecting MDMA (Ecstasy, XTC) at a cutoff level of 500 ng/ml or higher.

PERFORMANCE CHARACTERISTICS

1. Accuracy

The accuracy was determined by comparing the results from the MDMA Urine Test with the GC/MS data. This study was carried out in house, using eighty (80) blind labeled clinical urine specimens. The detailed data is shown in the table in this section.

The results agreed 100% with the MDMA GC/MS data of specimens at levels below 75% of the cutoff (negative) and above the cutoff (positive). Two (2) discrepancies were observed on the specimens with the GC/MS data between 75% of the cutoff and the cutoff.

The overall agreement was 97.5%.

GC/MS (ng/ml)		MDMA Test		Total	Agreement
		Positive	Negative		
0	Drug-free	0	40	40	100%
	<75% (0-375)	0	10	10	100%
	75%~Cutoff (375-500)	2	9	11	82%
	Cutoff~125% (500-625)	9	0	9	100%
	Positive (>625)	10	0	10	100%
Total		21	59	80	97.5%

2. Reproducibility

The reproducibility study was performed off-site at three (3) Physician's Office Laboratories (POL) and a clinical reference laboratory by personnel with diverse educational backgrounds and working experiences. One hundred and ten (110) MDMA-spiked urine samples containing six different levels of MDMA: 0, 257, 378, 615, 709, and 1417 ng/ml (determined by GC/MS), were used for this study. The results are summarized in the following table.

Samples	Test Site I	Test Site II	Test Site III	Test Site IV	Total	
0 ng/ml	Number	15	15	15	15	60
	Result	15-	15-	15-	15-	60-
257 ng/ml	Number	15	15	15	15	60
	Result	15-	15-	15-	15-	60-
378 ng/ml	Number	25	25	25	25	100
	Result	25-	25-	25-	25-	100-
615 ng/ml	Number	25	25	25	25	100
	Result	23+, 2-	23+, 2-	22+, 3-	24+, 1-	92+, 8-
709 ng/ml	Number	15	15	15	15	60
	Result	15+	14+, 1-	15+	15+	59+, 1-
1417 ng/ml	Number	15	15	15	15	60
	Result	15+	15+	15+	15+	60+

At the four evaluation sites, two hundred and twenty (220) devices tested with samples containing less than 378 ng/ml MDMA (75% of the cutoff) were negative (100% agreement). Among the one hundred (100) devices tested with samples containing 615 ng/ml MDMA (125% of the cutoff), ninety two (92) were positive and eight (8) were negative (92% agreement). For the sixty (60) devices tested with samples containing 709 ng/ml MDMA (150% of the cutoff), fifty nine (59) were positive and one (1) was negative (98.3% agreement). The sixty (60) devices tested with samples containing 1417 ng/ml MDMA were all positive. No significant within-day, between-day, or between-assay discrepancy was observed. The results obtained from the four evaluation sites agreed 97.5% with each other, indicating a high reproducibility of the device.

3. Cross-Reactivity

The cross-reactivity of the structurally related compounds with the device was studied. The following compounds were spiked into known drug-free urine pools and tested. Compounds produced positive results at a concentration below 10µg/ml are indicated in the following table:

Description	Concentration (ng/ml)
methylenedioxyamphetamine (MDA)	2000
Methylenedioxyethylamphetamine(MDEA)	1000

Compounds that did not produce positive responses at a concentration of 100µg/ml are indicated in the following table:

Description	Concentration (µg/ml)
L-amphetamine	100
d-amphetamine	100
L-methamphetamine	100
d-methamphetamine	100
Hydroxymethamphetamine (HAM)	100
Dihydroxymethamphetamine (HMMA)	100
N-methyl-1-(1-3-benzodioxol-5-yl)-2-butanamine(MBDB)	100

4. Interference

The following structurally unrelated analytes were spiked into known drug-free urine pools, as well as the MDMA positive (500 ng/ml) urine pools and were tested with the MDMA one step Urine Test. No interference was observed with either negative or positive specimens.

Compound	Conc. (µg/ml)	Compound	Conc. (µg/ml)
Acetaminophen	100	Oxalic Acid	100
Acetylsalicylic Acid	100	Oxazepam	100
Amikacin	100	Penicillin-G	100
Amitriptyline	100	Propoxyphene	100
Ampicillin	100	Pheniramine	100
Arterenal	100	Phencyclidine	100
Atropine	100	Phenylpropanolamine	100
Benzoic Acid	100	Ranitidine	100
Benzoylcocaine	100	Secobarbital	100
Caffeine	100	Salicylic Acid	100
(+)-Chlorpheniramine	100	11-nor-Δ ⁹ -THC-9-COOH	100
(+/-)-Chlorpheniramine	100	Thioridazine	100
Cocaine	100	Trifluoperazine	100
Codine	100	Albumin	100
Cortisone	100	Bilirubin	100
Dextromethorphan	100	Creatine	100
Methadone	100	Glucose	100
Morphine	100	Hemoglobin	100
Morphine-3-b-D-glucuronide	100	Vitamin C	100
Nortriptyline	100	Uric Acid	100

There is a possibility that other substances and/or factors not listed may interfere with the test and cause false results.

Effect of pH: Three (3) human urine specimens with the pH at 4.5, 6.5, and 8.5, were collected in house, separately. Each was spiked with MDMA to three levels, 375, 625, and 750ng/ml. All nine (9) specimens were tested with the MDMA Urine Test. The results indicated that the pH of human urine ranging from 4.5 to 8.5 did not affect the performance of the MDMA Urine Test.

Effect of Specific Gravity: Eight (8) human urine specimens with the specific gravity ranging from 1.002 to 1.035 g/ml were collected in house. Each was spiked with MDMA to five levels, 375, 625, 750, 1,000, and 1,500ng/ml. All those specimens were tested with the MDMA Urine Test, separately. The results indicated that the specific gravity of urine, ranging from 1.002 to 1.035, did not affect the performance of the MDMA Urine Test.

REFERENCES

- S-J. Peroutka ed. Ecstasy: The clinical, pharmacological and neurotoxicological effects of the drug MDMA. Kluwer Academic Publishers, 1990.
- Wilson, John, Abused Drugs II, a Laboratory Pocket Guide., AACCC Press. Washington, DC; p52, 1994.
- Department of Health and Human Services, Mandatory Guidelines for Federal Workplace Drug Testing Programs, Fed. Register. 53 (69): 11970 (1988).

15°C - 30°C	Temperature limitation		Use by YYYY-MM
	Batch/Lot code		In vitro diagnostic medical device
	Manufacturer		Catalog number
	Contains sufficient for < n > tests		Consult instructions for use
	Do not reuse		CE Mark
	Caution, consult accompanying documents		

LABSTIX DIAGNOSTICS PTY LTD.

SOUTH AFRICA DISTRIBUTOR
MADE IN USA



REF 2957

Tel.: +27 13 947 8049
Fax: +27 86 669 7760
Email: info@labstix.co.za