



MDMA (Ecstasy, XTC) RapiCard InstaTest

ONE STEP ASSAY

RAPID VISUAL RESULTS

FOR QUALITATIVE IN VITRO DIAGNOSTIC USE

Cat. No. 121030-1

INTENDED USE

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

This test provides only a 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 AND EXPLANATION OF THE TEST

MDMA is an abbreviation for the chemical methylenedioxyamphetamine. It has street many name including Ecstasy, X, XTC, E, Love Doves, Clarity, Adam, Disco Biscuits and Shamrocks, etc. It is a stimulant with hallucinogenic tendencies, described as an empathogen as it releases mood-altering chemicals, such as cartooning 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.^{1,2}

MDMA belongs to a family of man-made drugs; its relatives include MDA (methylenedioxymphetamine), the parent drug of MDMA, and MDEA (methylenedioxyethylamphetamine), also know as EVE. They all share 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 MDMA begin 30 minutes after intake. They peak in an hour and last for 2-3 hours. Sixty five percent (65%) of MDMA is excreted unchanged in urine: it is detectable in the urine for up to 3 days after use.^{1,2}

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 T line and a C line. The T line is coated with MDMA-BSA, and the C line is coated with goat anti-mouse antibody.

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

When an adequate amount of urine specimen is applied onto the sample pad of the device, the urine migrates by capillary action through the test strip. If the level of MDMA in the urine specimen is below the cutoff (500ng/ml), the T line should appear as a solid burgundy line. If the level of MDMA in the urine specimen is above the cutoff, the T line should not develop within the reading time of the device, 7 minutes.

The C line should bind to the colored mouse antibody conjugate and form a burgundy colored line regardless of the presence of MDMA.

REAGENTS AND MATERIALS SUPPLIED

- 25 test devices, each in a pouch with a dropper pipette and desiccant.
- One package insert

MATERIAL REQUIRED BUT NOT PROVIDED

- Specimen collection containers
- Timer
- Positive and Negative standards

STORAGE AND STABILITY

Store the kit at room temperature 59-86°F (15-30°C). 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 the kit and/or expose the kit to the temperature over 30°C.

SPECIMEN COLLECTION

- Each urine specimen must be collected in a clean container.
- Specimens may be kept at room temperature for 8 hours, at 2-8°C for up to 3 days and at -20°C or lower for prolonged storage. Do not mix specimens.

PRECAUTION

- The instructions must be followed to obtain accurate results.
- Do not open the sealed pouch, unless ready to operate the assay.
- Dispose of all specimens and used assay materials in a proper biohazard container.
- Do not use expired devices.

ASSAY PROCEDURE

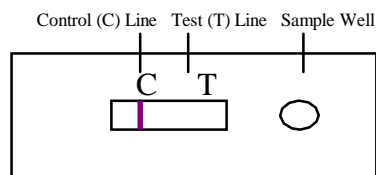
- Refrigerated specimens or other materials **must be equilibrated to room temperature before testing.**
- Remove the test device from pouch and place it on a flat surface. Label the device with specimen identification.
- Holding the dropper vertically, add four drops (about 160µl) of the specimen to the sample well marked as "S" on the device.
Note: If migration is not observed in 30 seconds in the results window, add one or two extra drops of urine specimen.
- Read the test result between four (4) to seven (7) minutes after adding the specimen.

IMPORTANT: Do not read test results after seven (7) minutes.

INTERPRETATION OF RESULTS

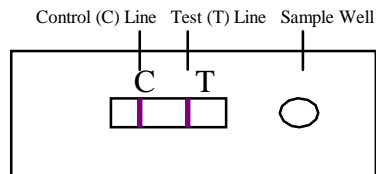
POSITIVE: Only the C line appears in the viewing window.

Note: Samples with positive results should be confirmed with a more specific method before a positive determination is made.

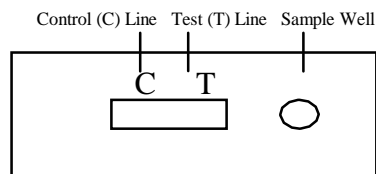
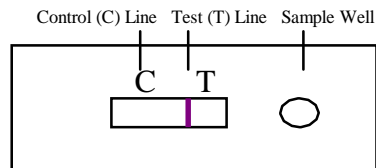


NEGATIVE: Both C line and T line appear in the viewing window.

Note: A faint line in the test region should be considered negative.



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



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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 the proper sample volume 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 testing 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

- 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.
- 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.

EXPECTED VALUES

This test is designed to detect the MDMA in human urine at a cutoff concentration of 500 ng/ml.

PERFORMANCE CHARACTERISTICS

1. Accuracy

One hundred ten (110) MDMA-spiked urine specimens calibrated with GC/MS method were used for the accuracy studies on this device. Among the 110 specimens, there were 55 negative and 55 positive. Within the negative specimens, 15 were negative (without MDMA), 15 were 50% below cutoff (257ng/ml MDMA), and 25 were 25% below cutoff (378ng/ml). Within the positive specimens, 25 were 25% above cutoff (615ng/ml), 15 were 50% above cutoff (709ng/ml), and 15 were positive (1417ng/ml). Studies were carried out in a clinical reference laboratory and three (3) Physician's Office Laboratories (POL) by personnel with diverse educational backgrounds and working experiences.

The results obtained from this MDMA Urine Test were 57 negative and 53 positive. The negative results agreed 100 % (55/55). The positive results agreed 96.4 % (53/55). The two (2) discrepancies were within the range of 25% above the cutoff level (615ng/ml). The correlation of the results obtained from the four evaluation sites was 98%.

		MDMA Test		
		negative	positive	Total
GC/MS test	negative (<500ng/ml)	55	0	55
	positive (>500ng/ml)	2	53	55
Total		57	53	110

2. Precision

The precision was determined by replicate assays of four different levels of samples with three different production lots. The devices were tested for five consecutive days five times each, for a total of 25 assays for each control.

The results obtained indicate 100% precision for the replicate within each lot and no appreciable inter-lot variation across the three different lots of devices.

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 with the MDMA Urine Test.

Compounds produced positive responses at a concentration below 10 μ g/ml were indicated in the following table:

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

Compounds did not produce positive results at a concentration below 100 μ g/ml were indicated in the following table:

Description	Concentration(μ g/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 (500ng/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.	Compound	Conc.
Acetaminophen	100 μ g/ml	Oxazepam	100 μ g/ml
Acetylsalicylic Acid	100 μ g/ml	Penicillin-G	100 μ g/ml
Amikacin	100 μ g/ml	Propoxyphene	100 μ g/ml
Amitriptyline	100 μ g/ml	Pheniramine	100 μ g/ml
Ampicillin	100 μ g/ml	Phencyclidine	100 μ g/ml
Arterenal	100 μ g/ml	Phenylpropanolamine	100 μ g/ml
Atropine	100 μ g/ml	Ranitidine	100 μ g/ml
Benzoic Acid	100 μ g/ml	Secobarbital	100 μ g/ml
Benzoylcgonine	100 μ g/ml	Salicylic Acid	100 μ g/ml
Caffeine	100 μ g/ml	11-nor- Δ^9 -THC-9-COOH	100 μ g/ml
(+)-Chlorpheniramine	100 μ g/ml	Thioridazine	100 μ g/ml
(+/-)-Chlorpheniramine	100 μ g/ml	Trifluoperazine	100 μ g/ml
Cocaine	100 μ g/ml	Albumin	200 μ g/ml
Codeine	100 μ g/ml	Bilirubin	100 μ g/ml
Cortisone	100 μ g/ml	Creatine	100 μ g/ml
Dextromethorphan	100 μ g/ml	Glucose	100 μ g/ml
Methadone	100 μ g/ml	Hemoglobin	200 μ g/ml
Morphine	100 μ g/ml	PH	5.0-9.0
Morphine-3-b-D-glucuronide	100 μ g/ml	Vitamin C	100 μ g/ml
Nortriptyline	100 μ g/ml	Uric Acid	100 μ g/ml
Oxalic Acid	100 μ g/ml		

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

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., AAC Press. Washington, DC; p52, 1994.

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See external label



2°C-30°C



Σ =25 or 50 tests

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