



ADVANCED QUALITY™ ONE STEP Ecstasy(MDMA) TEST

(Urine)

FOR *IN VITRO* DIAGNOSTIC USE ONLY

INTENDED USE

THE ADVANCED QUALITY™ ONE STEP ECSTASY(MDMA) TEST IS A RAPID, IMMUNOCHROMATOGRAPHIC ASSAY FOR THE DETECTION OF MDMA AND ITS METABOLITES IN HUMAN URINE. THE TEST IS USED TO SCREEN URINE FOR THE PRESENCE OF MDMA AND ITS METABOLITES AT A CUTOFF CONCENTRATION OF 500NG/ML. THE TEST IS INTENDED FOR USE BY HEALTHCARE PROFESSIONALS 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 spectrophotometry (GC/MS) is the preferred confirmatory method. Clinical considerations and professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are indicated.

SUMMARY AND EXPLANATION OF THE TEST

MDMA is an abbreviation for the chemical methylenedioxyamphetamine MDMA. 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 heart stroke.

MDMA belongs to a family of man-made drugs; its relatives include MDA (methylenedioxy MDMA), the parent drug of MDMA, and MDEA (methylenedioxyethyl MDMA), also know as EVE. They all share the MDMA-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.

PRINCIPLE OF THE PROCEDURE

This assay is a one-step lateral flow chromatographic immunoassay. The test device /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/strip, the urine migrates by capillary action through the test device/strip. If the level of MDMA in the urine specimen is below the cut-off (500ng/ml), the T line should appear as a solid burgundy line. If the level of MDMA in the urine specimen is above the cut-off, the T line should not develop within the reading time of the device/strip, 8minutes.

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

FOR STRIP TEST

1. Test strips individually foil pouched with a desiccant
2. Urine cups

3. Package insert

FOR CARD TEST

1. Test cards individually foil pouched with a desiccant
2. Plastic dropper
3. Package insert

MATERIALS REQUIRED BUT NOT PROVIDED

1. Urine collection containers (for card test)
2. Clock or Timer
3. Positive and negative urine control

STORAGE AND STABILITY

Store the kit at room temperature 2-30 . Each device/strip 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 .

SPECIMEN COLLECTION

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

PRECAUTION

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

ASSAY PROCEDURE

FOR STRIP TEST:

1. Bring all materials and specimens to room temperature.
2. Remove test strip from the sealed foil pouch.
3. Dip the test strip into the urine sample with the arrows pointing toward the specimen.
4. The urine level should reach the maximum line marked on the strip, but must not exceed the maximum line.
5. Hold the strip in the urine until a reddish color appears at the lower edge of the test membrane (approximately 10 seconds).
6. Withdraw the strip and place it face up on a clean, dry surface.
7. Read the result between 3 - 8 minutes after adding the sample.

FOR CARD TEST:

1. Bring all materials and specimens to room temperature.
2. Remove test card from the sealed foil pouch.
3. Place the test card on a flat dry surface.
4. Using the provided plastic dropper, dispense 3 drops of urine sample to the sample well of the test card. Start timing.
5. Read result between 3 - 8 minutes after adding the sample.

READING THE TEST RESULTS

Read test results between 3 - 8 minutes.

Do not interpret results after 8 minutes.

NEGATIVE Two (2) pink/purple bands form. In addition to the control band, a pink/purple band also appears in the test region.

Note: This immunoassay is a screening test. A negative result indicates the drug level is below the detection sensitivity. It is important to understand that concentrations of the drug below cut off may cause a faint "ghost line" to form in the test region. This "ghost line" should be considered a negative result.

POSITIVE One (1) pink/purple band appears in the control region. No band is found in the test region. This is an indication that the drug level is above the detection sensitivity level.

INVALID If there is no pink/purple band in the control area of the strip, the test result is invalid. Retest

the sample using a new device/strip.

Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly when preliminary results are positive. Positive results should be confirmed by an alternate method such as GC/MS.

QUALITY CONTROL

1. 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.

2. 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 cut-off concentration of the assay.

LIMITATIONS

1. There is a possibility that other substances and /or factor not listed in this instruction may interfere with the test and cause false results, e.g., technical or procedural errors.
2. Some adulterants such as bleach or other strong oxidizing agents may produce erroneous test results if added in the strip. When suspected, collect a fresh specimen and repeat the test with a new strip.

EXPECTED VALUES

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

PERFORMANCE CHARACTERISTICS

1. Accuracy

One hundred ten (110) MDMA-spiked urine specimens calibrated with GC/MS method were used for the accuracy studies in this strip. Among the 110 specimens, there were 55 negative and 55 positive. Within the negative specimens, 15 were negative (without MDMA), and 25 were 25% below cut-off (378ng/ml). Within the positive specimens, 25 were 25% above cut-off (615ng/ml), 15 were 50% above cut-off (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 cut-off 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.

TABLE 1 –Compounds produced positive responses at a concentration below 10ug/ml were indicated in the following table:

Description	Concentration(ng/ml)
Methylenedioxyamphetamine(MDA)	2000

MethylenedioxyethylMDMA(MDEA)

1000

TABLE 2 –Compounds did not produce positive results at a concentration below 100ug/ml were indicated in the following table:

Description	Concentration(ng/ml)
L-MDMA	100
d-MDMA	100
L-methMDMA	100
d- methMDMA	100
HydroxymethMDMA(HAM)	100
DihydroxymethMDMA(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	100µg/ml	Oxazepam	100µg/ml
Acetylsalicylic Acid	100µg/ml	Penicillin-G	100µg/ml
Amikacin	100µg/ml	Propoxyphene	100µg/ml
Amitriptyline	100µg/ml	Pheniramine	100µg/ml
Ampicillin	100µg/ml	Phencyclidine	100µg/ml
Arterenal	100µg/ml	Phenylpropanalamine	100µg/ml
Atropine	100µg/ml	Ranitidine	100µg/ml
Benzoic Acid	100µg/ml	Secobarbital	100µg/ml
Benzoyllecgonine	100µg/ml	Salicylic Acid	100µg/ml
Caffeine	100µg/ml	11-nor- ⁹ -THC-9-COOH	100µg/ml
(+)-Chlorpheniramine	100µg/ml	Thioridazine	100µg/ml
(+/-)-Chlorpheniramine	100µg/ml	Trifluoperaine	100µg/ml
Cocaine	100µg/ml	Albumin	200µg/ml
Codeine	100µg/ml	Bilirubin	100µg/ml
Cortisone	100µg/ml	Creatine	100µg/ml
Dextromethorphan	100µg/ml	Glucose	100µg/ml
Methadone	100µg/ml	Hemoglobin	200µg/ml
Morphine	100µg/ml	PH	5.0-9.0
Morphine-3-b-D-glucuronide	100µg/ml	Vitamin C	100µg/ml
Nortriptyline	100µg/ml	Uric Acid	100µg/ml
Oxalic Acid	100µg/ml		

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

REFERENCES

1. S-J. Peroutka ed. Ecstasy: The clinical, pharmacological and neurotoxicological effects of the drug MDMA. Kluwer Academic Publishers, 1990.
2. Wilson, John, Abused Drugs II, a Laboratory Pocket Guide., AAC Press. Washington, DC; p52, 1994.



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