DRG® MDMA (Ecstasy) Rapid Screen Test (RAP-4152)

USA: RUO

Revised 15 Jun 2008

For the rapid determination of MDMA and its metabolites in human urine

For *in vitro* use only. In the United States, this kit is intended for Research Use Only.

INTENDED USE

DRG® International, Inc., MDMA (Ecstasy) Screen Test Card and Test Strip devices are in vitro, lateral flow, immunochromatographic, qualitative urinary assays for the rapid detection of MDMA and its metabolites in human urine at the Substance Abuse Mental Health Services Administration (SAMHSA) cut-off level of 500 ng/ml. The tests are designed to obtain a visual, qualitative result and are intended for professional use only. They are not intended for quantitative results, nor for over-the-counter sale.
The MDMA (Ecstasy) Screen Test provides only preliminary analytical data. A more specific, alternative method is required to obtain a confirmed analytical result. SAMHSA has established gas chromatography / mass spectrometry (GC/MS) as 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 TEST

3, 4-methylenedioxy-n-methamphetamine (MDMA) is a psychoactive , neurotoxic hallucinogen structurally related to MDA, mescaline, methamphetamine and amphetamine. Though the drug is known for both for a rapid sense of exhilaration and its ability to relax users and create a sense of emotional closeness, short-term effects of MDMA use include confusion, severe anxiety, paranoia, depression, muscle tension, involuntary teeth clenching and tightening of the jaw, nausea, blurred vision, rapid eye movement, loss of depth perception, faintness, dilated pupils, dry mouth and throat, epileptic fit, irritability, poor concentration, forgetfulness and exhaustion. Long-term effects can include mood changes, disrupted sleep patterns, depression and psychosis. Some research suggests that even a few doses of the drug can cause permanent damage to cognitive functions such as learning and memory. MDMA destroys serotonin-producing neurons in the brain. Serotonin is a neurotransmitter associated with mood regulation, body temperature regulation and memory. Increased heart rate and hyperthermia due to MDMA use can lead to severe dehydration and heat exhaustion, muscle breakdown, hypertension, cardiovascular and kidney failure, heart attacks and strokes. This holds special risks for people with pre-existing circulatory or heart disease. The drug has also been known to cause liver damage. Alcohol potentiates the mental and physical side-effects of MDMA use because of its depressant and diuretic properties. Additional precautions in the use of MDMA are its potential effect on ability to drive a vehicle as well as its potential misuse as a “date-rape” drug and the associated sexually transmitted diseases.
The DRG® MDMA (Ecstasy) Screen Test is a rapid, visual, lateral flow, competitive immunochromatographic assay for the qualitative detection of MDMA and its metabolites in human urine. These in vitro screening tests are based immunoassay principles designed specifically for the assay and identification of MDMA and its metabolites at the SAMHSA cut-off level of 500 ng/ml or higher.

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PRINCIPLE OF THE PROCEDURE

The DRG® MDMA (Ecstasy) Screen Test is a competitive immunoassay in which chemically modified and bound MDMA conjugate competes with urinary MDMA and its metabolites for limited, specific MDMA antibody binding sites. Each test device contains a sample reaction unit, a pink-colored, antibody-colloidal gold conjugate unit pre-labeled with specific antibody, and a chromatographic membrane pre-coated with drug conjugate in the device test region.
When free drug is absent from urine or at concentrations lower than the urinary detection cut-off level, the pink-colored, antibody-colloidal gold conjugate is free to bind to the immobilized drug conjugate pre-coated on the chromatographic membrane test region. Consequently, a pink-colored band will form in the test region indicating a negative result. When drug is present in urine at concentrations at or exceeding the detection cut-off level, it will bind to limited epitopes on the pink-colored, antibody-colloidal gold conjugate, completely competing with drug conjugate in the test region. In such cases, no band forms in the test region, indicating a positive result.
The DRG® MDMA (Ecstasy) Screen Test also provides a built-in process control. A pink-colored band should always appear in the control region, regardless of the presence of any urinary MDMA and its metabolites. This pink-colored control band verifies that: 1) sufficient urine volume was added, and 2) proper flow was obtained. If the control band is missing, the test was not performed correctly or failed to function correctly. In summary, negative urine will produce two pink-colored bands, one in the control region and one in the test region. Positive urine will produce one pink-colored band in the control region only.

REAGENTS AND MATERIALS SUPPLIED

Test device with the following components: a sample reaction unit, a pink-colored, colloidal gold conjugate unit, and a chromatographic membrane unit; a disposable sample pipette comes with the test card; test instructions.

MATERIALS REQUIRED BUT NOT PROVIDED

- Urine sample collection containers
- Timer or clock

WARNINGS AND PRECAUTIONS

For *in vitro* use.

- Avoid cross contamination of urine samples by using a new sample collection container and pipette for each urine sample.
- Urine specimens may be potentially infectious. Avoid contact with skin by wearing gloves and proper laboratory attire. Properly handle and dispose of all used test devices in an approved biohazard container.
- Do not use a test device beyond the expiration date imprinted on the outside of the foil pouch.

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STORAGE AND STABILITY

The test devices supplied can be stored at room temperature or refrigerated (2-28°C) and will remain stable until the expiration date. **Do Not Freeze.**

SAMPLE COLLECTION AND PREPARATION

The fresh urine samples should be collected in a clean, dry container such that same-day testing may be performed. Urine specimens may be refrigerated at 2-8°C for 48hours, or frozen at -20°C for assaying at a later date. Specimens that have been refrigerated or frozen must be equilibrated to room temperature before testing. Urine samples exhibiting visible precipitates should be filtered, centrifuged or allowed to settle so that clear aliquots can be obtained for testing.

ASSAY PROCEDURE

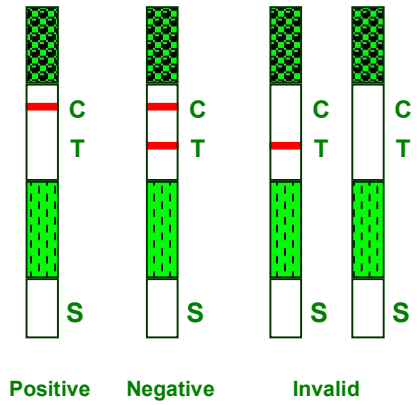
Do not open foil pouch until ready to begin testing. Refrigerated test device should be allowed to equilibrate to room temperature (15-28°C) before pouch is opened.
Remove the test device from the sealed foil pouch by tearing along the notch.
FOR TEST STRIP: Immerse the strips in urine with the arrow end pointing towards the urine. Do not introduce urine above the maximum level, as indicated by the arrows.
FOR TEST CARD: Draw the urine sample into the pipette and dispense four drops (approximately 0.2ml) into the sample well of test device.
Read the test result at five minutes.

IMPORTANT: In order to prevent an incorrect reading, do not read the test results after more than 10 minutes. After 10 minutes, the intensity of the colored lines may change or a new line may appear. To avoid confusion, discard the test device after interpreting the result.

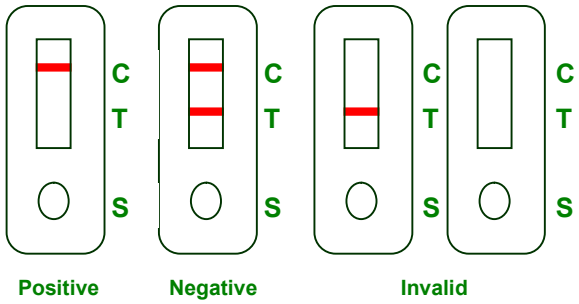
INTERPRETATION OF RESULTS

Negative: Two pink-colored bands appear, one in the control region and one in the test region. A negative result indicates free drug is absent from urine or at concentrations lower than the detection cut-off level of the test.
Positive: One colored band appears in the control region with no apparent band appearing in the test region. A positive result indicates free drug is present in urine at concentrations at or exceeding the detection cut-off level of the test.
Invalid: No band appears in the control region, or a pink-colored band appears in the test region only. An invalid test result may be due to improper assay procedures or damage to the device. With an invalid result, the assay is inconclusive and the specimen should be re-tested using a new test device.
Note: The test band intensity may be weaker or stronger than that of the control band, but a very faint band in the test region indicates that the free drug concentration is near the cut-off level in the urine. The specimen should be re-tested or confirmed with a more specific method before a positive determination is made.

TEST STRIPS



TEST CARDS



PROCESS AND QUALITY CONTROL

Good laboratory practice requires use of control materials that ensure proper test device performance and reliability. Quality control standards are available for the validation of device functionality from commercial sources such as BioRad, Sigma and Biopool. To test the quality of control standards, use the assay procedure for testing urine samples. The SAMHSA recommended guidelines for drugs of abuse screening test devices indicate that controls should contain the drug of abuse analyte at levels at least 25% above SAMHSA cut-off values.

AFTER TESTING

Urine specimens may be potentially infectious. Avoid contact with skin by wearing gloves and proper laboratory attire. Properly handle and dispose of all used test devices in an approved biohazard container. Residual urine should be disposed of in a medically approved manner after the completion of all testing, including the confirmatory assay.

PERFORMANCE CHARACTERISTICS

SENSITIVITY

The DRG® MDMA (Ecstasy) Screen Test has been designed for the detection of MDMA and its metabolites in urine at the detection sensitivity of 500 ng/ml. In sensitivity studies performed, concentrations of MDMA equal to or lower than 300 ng/ml were identified as negative for all samples. Concentrations of MDMA equal to or higher than 500 ng/ml were identified as positive results for all samples. Thus, the cut-off level of the DRG® MDMA (Ecstasy) Screen Test was determined to be 500 ng/ml for both Test Card and Test Strip devices.

PRECISION

In order to determine the precision of both the DRG® MDMA (Ecstasy) Screen Test Card and Test Strip devices, both within-lot and inter-lot reproducibility studies were performed. Results of within-lot reproducibility studies clearly showed excellent repeatability for all positive and negative urine samples, using one lot of DRG® MDMA (Ecstasy) Screen Test Card devices and one of Test Strip devices. The results of inter-lot reproducibility studies clearly demonstrated that there was no appreciable inter-lot variation when testing both positive and negative samples across three different lots of DRG® MDMA (Ecstasy) Screen Test Card and Test Strip devices.

SPECIFICITY STUDY

Device specificity was tested against compounds related to, or not associated with, MDMA, prepared in drug-free, normal human urine. The following compounds produced positive results with the DRG® MDMA (Ecstasy) Screen Test at levels at or greater than the concentrations listed below.

3, 4-methylenedioxy-n-methamphetamine (MDMA)	500ng/ml
Methylenedioxyamphetamine (MDA)	1000 ng/ml
Mehylenedioxethylamphetamine (MDEA)	500 ng/ml

The following structurally related compounds were found to produce negative results with the DRG® MDMA (Ecstasy) Screen Test when tested at levels of up to 100 µg drug/ml (100,000 ng drug/ml).

l-Amphetamine
d-Amphetamine
l-Methamphetamine
d-Methamphetamine
hydroxymehtamphetamine (HMA)
dihydroxymehtamphetamine (HHMA)
N-methyl-1-(1,3-benzodioxol-5-yl)-2-butanamine (MBDB)

The following compounds were found to have no effect on negative results when tested at levels of up to 100 µg drug/ml (100,000 ng drug/ml).

Acetaminophen (N-Acetyl-p-aminophenol)
Acetone
Albumin
Amitriptyline
Ampicillin
Aspartame (Asp-Phe Methyl Ester)
Aspirin (Acetylsalicylic Acid)
Atropine
Benzocaine (Ethyl p-Aminobenzoate)
Bilirubin
Caffeine
Chloroquine
(+)-Chlorpheniramine
(+/-)-Chlorpheniramine
Creatine
Dexbrompheniramine ([+]-Brompheniramine)
4-Dimethylaminoantipyrine
Dopamine (3-Hydroxytyramine)
Doxylamine
(+/-)-Ephedrine
(-)-Ephedrine
(+)-Epinephrine
Erythromycin
Ethanol
Furosemide
Glucose
Guaiacol glyceryl ether
Hemoglobin
Imipramine
(+/-)-Isoproterenol
(1R,2S)-(-)-N-Methyl-Ephedrine
Lidocaine
(+)-Naproxen
(+/-)-Norephedrine
Penicillin-G (Benzylpenicillin)
Pheniramine
Phenothiazine (Thiodiphenylamine)
L-Phenylephrine
β-Phenylethylamine
Procaine
Promethazine
Quinidine
Ranitidine
Sulindac
Tyramine
Vitamin C (L-Ascorbic Acid)

LIMITATIONS OF PROCEDURE

This diagnostic test is designed for the medical or forensic in vitro detection of MDMA and its metabolites in human urine.
This diagnostic test only provides a qualitative screening for MDMA in urine. It is not to be used for the quantitative determination of MDMA in urine. A positive result with this test indicates only the presence of MDMA and its metabolites and should be confirmed by GC/MS. It does not indicate intoxication.
There is a possibility of false positive results due to user error or the presence of interfering factors in urine.
See "SPECIFICITY STUDY" for substances that produce positive results at high concentrations and those substances which do not interfere with test performance.
Adulterants, such as bleach or other strong oxidizing agents, may produce erroneous test results when added to urine specimens, regardless of the analysis method used. If an adulteration is suspected, a fresh urine specimen should be used.

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