




MDMA Ecstasy Test Cassette (Urine)

IVD For *in vitro* diagnostic use only.

 Store at 2-30 °C



INTENDED USE

Urine-based tests for MDMA Ecstasy abuse which is a lateral flow chromatographic immunoassay for the qualitative detection of MDMA Ecstasy in urine at 1000 ,500 , 300 (ng/ml) of cut-off concentrations when using Methylenedioxymethamphetamine as calibrator.

PRINCIPLE

The MDMA Ecstasy Test Cassette (Urine) is an immunoassay based on the principle of competitive binding. MDMA Ecstasy which may be present in the urine specimen compete against MDMA Ecstasy conjugate for binding sites on their specific antibody.

During testing, a urine specimen reacts with antibodies conjugated to colored particles and precoated on the sample pad, the mixture then migrates upward by capillary action. MDMA Ecstasy , if present in the urine specimen below its cut-off concentration, will not saturate the binding sites of its specific antibody. The antibody will then react with the MDMA Ecstasy conjugate at the test region and a visible colored line will show up in the test line region of the strip. The presence of MDMA Ecstasy above the cut-off concentration will saturate all the binding sites of the antibody. Therefore, the colored line will not form in the test line region.

A drug-positive urine specimen will not generate a colored line in the specific test line region of the strip because of drug competition, while a drug-negative urine specimen will generate a line in the test line region because of the absence of drug competition. To serve as a procedural control, a colored line will always appear at the control line region, indicating that proper volume of specimen has been added and membrane wicking has occurred.

PRECAUTIONS

- For *in vitro* diagnostic use only. Do not use after the expiration date.
- The test device should remain in the sealed pouch until use.
- All specimens should be considered potentially hazardous and handled in the same manner as an infectious agent.
- The used test device should be discarded according to federal, state and local regulations.

STORAGE AND STABILITY

The kit can be stored at room temperature or refrigerated (2-30°C). The test device is stable through the expiration date printed on the sealed pouch. The test device must remain in the sealed pouch until use. **DO NOT FREEZE**. Do not use beyond the expiration date.

SPECIMEN COLLECTION AND PREPARATION

Urine Assay

The urine specimen must be collected in a clean and dry container. Urine collected at any time of the day may be used. Urine specimens exhibiting visible precipitates should be centrifuged, filtered, or allowed to settle to obtain a clear supernatant for testing.

Specimen Storage

Urine specimens may be stored at 2-8°C for up to 48 hours prior to testing. For prolonged storage, specimens may be frozen and stored below -20°C. Frozen specimens should be thawed and mixed well before testing.

MATERIALS

Materials Provided

- Test Cassettes.
- Droppers.
- Package Insert.

Materials Required But Not Provided

- *Specimen collection container.*
- Timer.

DIRECTIONS FOR USE

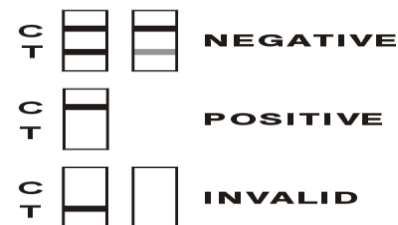
Allow the test device, urine specimen, and/or controls to

equilibrate to room temperature (15-30°C) prior to testing.

1. Bring the pouch to room temperature before opening it. Remove the test device from the sealed pouch and use it as soon as possible.
2. Place the test device on a clean and level surface. Hold the dropper vertically and transfer **3 full drops of urine** (approx. 120µL total volume) to the specimen well (S) of the test device, and then start the timer. Avoid trapping air bubbles in the specimen well (S). See the illustration below.
3. Wait for the colored lines(s) to appear. The results should be **read at 5 minutes**. Do not interpret results after 8 minutes.

INTERPRETATION OF RESULTS

(Please refer to the illustration below)



NEGATIVE:* A colored line in the control region (C) and a colored line in the test region (T) indicates a negative result. This indicates that the drug concentration in the urine specimen is below the designated cut-off level

***NOTE:** The shade of color in the test region (T) may vary, but it should be considered negative whenever there is even a faint colored line.

POSITIVE: A colored line in the control region (C) but no line in the test region (T) indicates a positive result. This indicates that the drug concentration in the urine specimen exceeds the designated cut-off .

INVALID: Control line fails to appear. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test using a new test panel. If the problem persists, discontinue using the lot immediately and contact your local distributor.

QUALITY CONTROL

A procedural control is included in the test. A red line appearing in the control region (C) is considered an internal procedural control. It confirms sufficient specimen 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.

LIMITATIONS

1. The MDMA Ecstasy Test Cassette (Urine) 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.^{1,2,3}
2. There is a possibility that technical or procedural errors, as well as other interfering substances in the urine specimen may cause erroneous results.
3. Adulterants, such as bleach and/or alum, in urine specimens may produce erroneous results regardless of the analytical method used. If adulteration is suspected, the test should be repeated with another urine specimen.
4. A Positive result does not indicate level or 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. Test does not distinguish between drugs of abuse and certain medications.

PERFORMANCE CHARACTERISTICS

Accuracy

The accuracy of the MDMA Ecstasy Test Cassette was compared and checked against commercially available tests with a threshold value at the same cut-off levels. Urine samples taken from volunteers claiming to be non-users were examined under both tests. The results were > 99.9% in agreement.

Reproducibility

The reproducibility of the MDMA Ecstasy Test Cassette

was verified by blind tests performed at four different locations. Samples with drug/metabolite concentration at 50% of the cut-off were all determined to be negative, while samples with drug/metabolite concentration at 200% of cut-off were determined to be positive.


Precision

















Test precision was determined by blind tests with control solutions. Control with drug/metabolite concentration at 50% of the cut-off yielded negative results, and controls with drug/metabolite concentration at 150% of the cut-off yielded positive results.

Specificity

The following table lists the concentration of compounds (ng/mL) that are detected positive in urine by the MDMA Ecstasy Test Cassette (Urine) at 5 minutes.

MDMA 1000	CON.(ng/mL)
3,4-Methylenedioxyamphetamine(MDMA)	1,000
3,4-Methylenedioxyamphetamine (MDA)	12,500
3,4-Methylenedioxyethylamphetamine(MDEA)	500
Paramethoxyamphetamine (PMA)	100,000
Paramethoxymethamphetamine (PMMA)	20,000
MDMA 500	CON.(ng/mL)
3,4-Methylenedioxyamphetamine(MDMA)	500
3,4-Methylenedioxyamphetamine (MDA)	6,250
3,4-Methylenedioxyethylamphetamine(MDEA)	156
Paramethoxyamphetamine (PMA)	50,000
Paramethoxymethamphetamine (PMMA)	10,000
MDMA 300	CON.(ng/mL)
3,4-Methylenedioxyamphetamine(MDMA)	300
L-Methamphetamine	75,000
3,4-Methylenedioxyamphetamine (MDA)	1,250
3,4-Methylenedioxyethylamphetamine(MDEA)	125
Paramethoxyamphetamine (PMA)	25,000
Paramethoxymethamphetamine (PMMA)	3,750

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 REF	Catalogue Number		Temperature limit
 IVD	In Vitro diagnostic medical device		Caution
 Σ	Contains sufficient for <n> tests and Relative size		Consult instructions for use (IFU)
 LOT	Batch code		Manufacturer
	Do not re-use		Use-by date
	Manufacturer fax number		Do not use if package is damaged
	Manufacturer telephone number		Date of Manufacture
	Keep away from sunlight		Keep dry