INTENDED USE

The MET One Step Methamphetamine Test Device (Urine) is a lateral flow chromatographic immunoassay for the detection of Methamphetamine in human urine.

SUMMARY

Methamphetamine is an addictive stimulant drug that strongly activates certain systems in the brain. Methamphetamine is closely related chemically to Amphetamine, but the central nervous system effects of Methamphetamine are greater. Methamphetamine is made in illegal laboratories and has a high potential for abuse and dependence. The drug can be taken orally, injected, or inhaled. Acute higher doses lead to enhanced stimulation of the central nervous system and induce euphoria, alertness, reduced appetite, and a sense of increased energy and power. Cardiovascular responses to Methamphetamine include increased blood pressure and cardiac arrhythmias. More acute responses produce anxiety, paranoia, hallucinations, psychotic behavior, and eventually, depression and exhaustion.

The effects of Methamphetamine generally last 2-4 hours, and the drug has a half-life of 9-24 hours in the body. Methamphetamine is excreted in the urine primarily as Amphetamine, and oxidized and deaminated derivatives. However, 10-20% of Methamphetamine is excreted unchanged. Thus, the presence of the parent compound in the urine indicates Methamphetamine use. Methamphetamine is generally detectable in the urine for 3-5 days, depending on urine pH level.

The MET One Step Methamphetamine Test Device (Urine) is a rapid urine screening test that can be performed without the use of an instrument. The test utilizes a monoclonal antibody to selectively detect elevated levels of Methamphetamine in urine. The MET One Step Methamphetamine Test Device (Urine) yields a positive result when the Methamphetamine in urine exceeds 1,000 ng/mL.

PRINCIPLE

The MET One Step Methamphetamine Test Device (Urine) is an immunoassay based on the principle of competitive binding. Drugs which may be present in the urine specimen compete against the drug conjugate for binding sites on the antibody.

During testing, a urine specimen migrates upward by capillary action. Methamphetamine, if present in the urine specimen below 1,000 ng/mL, will not saturate the binding sites of antibody coated particles in the test device. The antibody coated particles will then be captured by immobilized Methamphetamine conjugate and a visible colored line will show up in the test line region. The colored line will not form in the test line region if the Methamphetamine level exceeds 1,000 ng/mL because it will saturate all the binding sites of anti-Methamphetamine antibodies.

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

REAGENTS

The test device contains mouse monoclonal anti- Methamphetamine antibody-coupled particles and Methamphetamine-protein conjugate. A goat antibody is employed in the control line system.

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 STORAGE

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 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 assay. For prolonged storage, specimens may be frozen and stored below -20°C. Frozen specimens should be thawed and mixed before testing.

MATERIALS

Materials Provided

- Test devices
- Disposable specimen droppers
- Package insert

Materials Required But Not Provided

- Specimen collection container
- Timer

DIRECTIONS FOR USE

Allow test device, urine specimen, and/or controls to reach 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. 100ul) 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 red line(s) to appear. The result should be **read at 5 minutes**. It is important that the background is clear before the result is read. Do not interpret the result after 10 minutes.

INTERPRETATION OF RESULTS

POSITIVE RESULT:

Only one colored band appears in the control region (C). No apparent colored band appears in the test region (T).

NEGATIVE RESULT:

Two colored bands appear on the membrane. One band appears in the control region (C) and another band appears in the test region (T).

INVALID RESULT:

Control band fails to appear. Results from any test which has not produced a control band at the specified reading time must be discarded. Please review the procedure and repeat with a new test. If the problem persists, discontinue using the kit immediately and contact your local distributor.

NOTE:

1. The intensity of the color in test region (T) may vary depending on the concentration of aimed substances present in the specimen. Therefore, any shade of color in the test region should be considered negative. Besides, the concentration level can not be determined by this qualitative test.
2. Insufficient specimen volume, incorrect operation procedure, or performing expired tests are the most likely reasons for control band failure.

LIMITATION

1. The MET One Step Methamphetamine Test Device (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]
2. It is possible 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 indicates presence of the drug or its metabolites but does not indicate level of 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

A side-by-side comparison was conducted using the MET One Step Methamphetamine Test Device (Urine) and a leading commercially available MET rapid test. Testing was performed on 234 clinical specimens. Ten percent of the specimens employed were either at -25% or +25% level of the cut-off concentration of 1,000 ng/mL Methamphetamine. Presumptive positive results were confirmed by GC/MS. The following results were tabulated:

Method		Other MET Rapid Test		Total Results
MET One Step Test Device	Results	Positive	Negative	
	Positive	99	0	99
	Negative	1	134	135
Total Results		100	134	234
% Agreement with this Rapid Test Kit		99.0%	100%	99.6%

When compared at 1,000 ng/mL cut-off with GC/MS, the following results were tabulated:

Method		GC/MS		Total Results
MET One Step Test Device	Results	Positive	Negative	
	Positive	89	6	95
	Negative	1	138	139
Total Results		90	144	234
% Agreement with GC/MS Analysis		98.9%	95.8%	97.0%

Analytical Sensitivity

A drug-free urine pool was spiked with Methamphetamine at the following concentrations: 0 ng/mL, 500 ng/mL, 750 ng/mL, 1,000 ng/mL, 1,250 ng/mL and 1,500 ng/mL. The result demonstrates >99% accuracy at 50% above and 50% below the cut-off concentration. The data are summarized below:

MET Concentration (ng/mL)	Percent of Cut-off	n	Visual Result	
			Negative	Positive
0	0	20	20	0
500	-50%	20	20	0
750	-25%	20	14	6
1,000	Cut-off	20	10	10
1,250	+25%	20	1	19
1,500	+50%	20	0	20

Analytical Specificity

The following table lists compounds that are positively detected in urine by the MET One Step Methamphetamine Test Device (Urine) at 5 minutes.

Compound	Concentration (ng/mL)
ρ-Hydroxymethamphetamine	30,000
D-Methamphetamine	1,000
L-Methamphetamine	8,000
(±)-3,4-Methylenedioxymethamphetamine	2,000
Mephentermine	50,000

Index or Symbols

	Attention, see instructions for use		Tests per Kit		Manufacturer
IVD	For *in vitro*		Use by	2	Do not reuse
	Store between 2 - 30°C	LOT	Lot Number	REF	Catalogue Number

CE

Deniz Biyokimya Ürünleri Dış Tic. A.Ş.
Fatih Mh. 1191. Sk. No:5/2 Guzelemir
35410 IZMIR / TURKIYE