One Step
Methamphetamine Test Device (Urine)
Package Insert

(Catalog Number: 1186-C)

BIOMERICA

A rapid, one step test for the qualitative detection of Methamphetamines in human urine.

For professional in vitro diagnostic use only.

INTENDED USE

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

SUMMARY

Methamphetamine is a potent sympathomimetic agent with therapeutic applications. The drug can be taken orally, injected, or inhaled. Acute higher does 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 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 One Step Methamphetamine Test Device (Urine) yields a positive result when the methamphetamine in urine reaches 1000 ng/mL. This is the suggested screening cut-off for positive specimens set by the Substance Abuse and Mental Health Services Administration (SAMHSA, USA).

PRINCIPLE

The 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 1000 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 is at or above 1000 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 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 if the test has been performed properly.

REAGENTS

The test device contains anti-methamphetamine particles and methamphetamine conjugate coated on the membrane.

PRECAUTIONS

- For professional *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 test device should be discarded in a proper biohazard container after testing.

STORAGE AND STABILITY

Store as packaged in the sealed pouch at 4-30°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 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.

PROCEDURE

Materials Provided

- Test devices
- Disposable specimen droppers
- Package insert

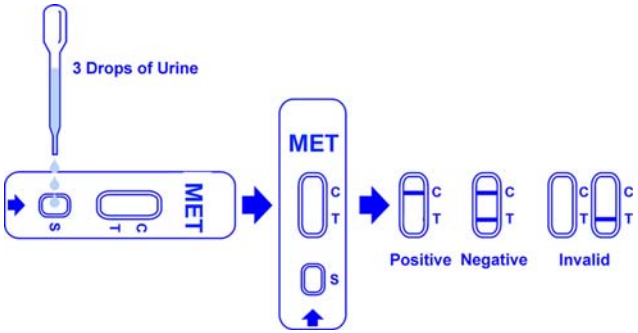
Materials Required But Not Provided

- Specimen collection container
- Timer

DIRECTIONS FOR USE

Allow test device, urine specimen, and/or controls to 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. 100µl) 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

(Please refer to the illustration above)

POSITIVE: One red line appears in the control region (C). No line appears in the test region (T). This positive result indicates that the methamphetamine concentration is at or above the detectable level (1000 ng/mL).

NEGATIVE:* Two lines appear. One red line should be in the control region (C), and another apparent red or pink line should be in the test region (T). This negative result indicates that the methamphetamine concentration is below the detectable level (1000 ng/mL).

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 device. If the problem persists, discontinue using the lot immediately and contact your local distributor.

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

QUALITY CONTROL

A procedural control is included in the test. A red line appearing in

the control region (C) is considered as an internal procedural control. It confirms sufficient specimen volume and correct procedural technique. A clear background is also required.

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.

LIMITATION

1. The One Step Methamphetamine Test Device (Urine) provides only a preliminary analytical result. A secondary analytical method must be used to obtain a confirmed result. Gas chromatography and mass spectrometry (GC/MS) are the preferred confirmatory methods (1).
2. The One Step Methamphetamine Test Device (Urine) is a qualitative screening assay and can not determine either the drug concentration in the urine or the level of intoxication.
3. It is possible that technical or procedural errors, as well as other interfering substances in the urine specimen may cause erroneous results.
4. 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.
5. Certain medications containing opiates or opiate derivatives may produce a positive result. Additionally, foods and tea containing poppy products may also produce a positive result.

PERFORMANCE CHARACTERISTICS

Sensitivity

The Substance Abuse and Mental Health Services Administration (SAMHSA) has set the screening cut-off for positive specimens at 1000 ng/mL for methamphetamine (2). The One Step Methamphetamine Test Device (Urine) has been shown to detect 1000 ng/mL of methamphetamine in urine at 5 minutes.

Specificity

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

Table 1.

Compound	Concentration (ng/mL)	Cross-Reactivity (%)
D-Amphetamine	30,000	3.3
D,L-Amphetamine sulfate	100,000	1
(±) Ephedrine	100,000	1
(-) Ephedrine	75,000	1.3
D-Methamphetamine	1,000	100
p-OH-Methamphetamine	10,000	10
Methylenedioxyamphetamine	100,000	1

Cross-Reactivity

A study was conducted to determine the cross-reactivity of the test with compounds in urine not associated with methamphetamines. The following compounds show no cross-reactivity when tested with the One Step Methamphetamine Test Device (Urine) at a concentration of 100 µg/mL (Table 2).

Table 2. Non Cross-Reacting Compounds

Acetamidophen
Acetophenetidin(Phenacetin)
N-Acetylprocainamide
Acetylsalicylate
Aminopyrine
Amitryptyline
Amobarbital
Amoxapine
Amoxicillin
Apomorphine
Aspartame
Atropine
Benzilic acid
Benzoic acid
Benzoylecgonine
Benzphetamine
Butabarbital
Cannabidiol
Chloralhydrate
Chloramphenicol
Chlordiazepoxide
Chlorothiazide
Chlorpromazine
Chlorquine
Cholesterol
Clomipramine
Clonidine
Cocaine hydrochloride
Codeine
Cortisone
(-) Cotinine
Creatinine
Deoxycorticosterone
Dextromethorphan
Diazepam
Diclofenac
Diethylpropion
Diflunisal
Digoxin
Diphenhydramine
Domperidone
Doxylamine
Ecgonine hydrochloride
Ecgonine methylester
Nifedipine
Norcodein
Norethindrone
Noroxymorphone
D-Norpropoxyphene
Noscapine
Nylidrin
D,L-Octopamine
Erythromycin
β-Estradiol
Estrone-3-sulfate
Ethyl-p-aminobenzoate
Fenoprofen
Furoxmide
Gentisic acid
Glucuronide
Glutethimide
Guaifenesin
Hippuric acid
Hydralazine
Hydrochlorothiazide
Hydrocodone
Hydrocortisone
Hydromorphone
O-Hydroxyhippuric acid
3-Hydroxytyramine
Ibuprofen
Imipramine
Iproniazid
(-) Isoproterenol
Isoxsuprine
Ketamine
Ketoprofen
Labetalol
Levorphanol
Lidoccaine
Loperamide
Loxapine succinate
Maprotiline
Meperidine
Meprobamate
Methadone
Methaqualone
Methylphenidat
Methyprylon
Morphine-3-β-D-glucuronide
Nalidixic acid
Nalorphine
Naloxone
Naltrexone
Naproxen
Niacinamide
Promethazine
D,L-Propanolol
Propiomazine
D-Propoxyphene
Quinidine
Quinine
Ranitidine
Salicylic acid
Oxalic acid
Oxazepam
Oxolinic acid
Oxycodone
Oxymetazoline
Oxymorphone
Papaverine
Penicillin-G
Pentazocaine
Pentobarbital
Perphenazine
Phencyclidine
Phenelzine
Phendimetrazine
Phenobarbital
Phentermine
Phentoin
L-Phenylethlamine
β-Phenylethlamine
Phenylpropanolamine
Prednisolone
Prednisone
Procaine
Promazine
Secobarbital
Serotonin
Sulfamethazine
Sulindac
Temazepam
Tetracycline
Tetrahydrocortisone
Tetrahydrozoline
Δ^9-THC-COOH
Thebaine
Thiamine
Thioridazine
D,L-Thyroxine
Tolbutamide
Triamterene
Trifluoperazine
Trimethoprim
Trimipramine
Tryptamine
D,L-Tyrosine
Uric acid
Verapamil
Zomepirac

BIBLIOGRAPHY

1. Baselt RC. Disposition of Toxic Drugs and Chemicals in Man. 2nd Ed. Biomedical Publ., Davis, CA. 1982; 488
2. Hawwks RL, CN Chiang. *Urine Testing for Drugs of Abuse*. National Institute for Drug Abuse (NIDA), Research Monograph 73, 1986

	Storage Temperature	EC REP	Authorized Representative
LOT	Lot Code		Caution, See Instructions
	Expiration	IVD	For in vitro diagnostic use
	Manufacturer	REF	Catalog No.

Biomerica, Inc., 1533 Monrovia Avenue
Newport Beach, CA 92663 USA

EC REP

according to IVDD 98/79/ EC
MDSS
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