One Step
Amphetamine Test Device (Urine)
Package Insert

(Catalog Number: 1182-C)

BIOMERICA

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

For professional in vitro diagnostic use only.

INTENDED USE

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

SUMMARY

Amphetamines are a class of potent sympathomimetic agents with therapeutic applications. They are chemically related to the human body's natural catecholamines: epinephrine and norepinephrine. 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 amphetamines include increased blood pressure and cardiac arrhythmias. More acute responses produce anxiety, paranoia, hallucinations, and psychotic behavior. The effects of amphetamines generally last 2-4 hours following use, while the drug has a half-life of 4-24 hours in the body. About 30% of amphetamines are excreted in the urine in unchanged form, with the remainder as hydroxylated and deaminated derivatives.

The One Step Amphetamine 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 amphetamines in urine. The One Step Amphetamine Test Device (Urine) yields a positive result when amphetamines in urine reach 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 Amphetamine Test Device (Urine) is a rapid chromatographic 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. Amphetamines, if present in the urine specimen below 1000 ng/mL, will not saturate the binding sites of the antibody coated particles in the test device. The antibodies coated particles will then be captured by immobilized amphetamine 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 amphetamine level is at or above 1000 ng/mL because it will saturate all the binding sites of anti-amphetamine 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-amphetamine particles and amphetamine 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 to settle to obtain 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

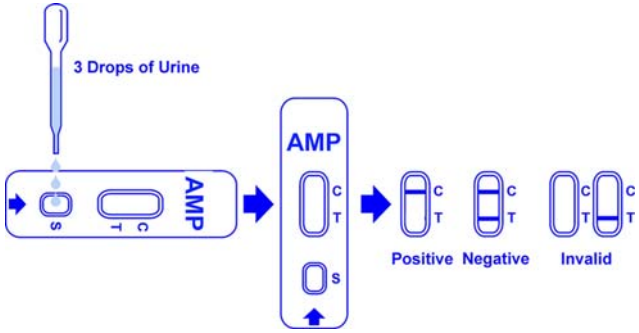
Materials Required But Not Provided

- Specimen collection container
- Timer

DIRECTIONS FOR USE

Allow the test strip, 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 amphetamine 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 amphetamine 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 always be considered as 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.

LIMITATIONS

1. The One Step Amphetamine 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 Amphetamine 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 amphetamines (2). The One Step Amphetamine Test Device (Urine) has been shown to detect 1000 ng/mL of amphetamines in urine at 5 minutes.

Specificity

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

Table 1.

Compound	Concentration (ng/mL)
Amphetamine	1,000
D,L-Amphetamine sulfate	2,000
Methylenedioxyamphetamine	500
β-Phenethylamine	45,000
Phentermine	150
3-OH Tyramine	90,000
Tyramine	30,000
Tryptamine	35,000

Cross-Reactivity

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

Table 2. Non Cross-Reacting Compounds

Acetamidophen
Acetylsalicylate
Aminopyrine
Amitryptyline
Amobarbital
Amoxapine
Amoxicillin
L-Amphetamine
Apomorphine
Ascorbic acid
Aspartame
Atropine
Benzocaine
Benzoylecgonine
Benzphetamine
Butabarbital
Cannabidiol
Chloralhydrate
Chloramphenicol
Chlordiazepoxide
Chlorothiazide
Chlorpromazine
Chlorquine
Cholesterol
Clomipramine
Clonidine
Cocaine
Cortisone
(-) Cotinine
Creatinine
Deoxycorticosterone
Dextromethorphan
Diazepam
Diethylpropion
Diflunisal
Digoxin
Diphenhydramine
Doxylamine
Ecgonine
Ecgonine methylester
(+) Ephedrine
(±) Ephedrine
(-) Ephedrine
(-) ψ Ephedrine
Erythromycin
β-Estradiol
Estrone-3-sulfate
Ethyl-p-aminobenzoate
Fenoprofen
Furoxmide
Gentisic acid
Oxalic acid
Oxazepam
Oxolinic acid
Oxycodone
Oxymetazoline
Oxymorphone
p-Hydroxymethamphetamine
Papaverine
Penicillin-G
Pentazocaine
Pentobarbital
Perphenazine
Phencyclidine
Phenelzine
Phendimetrazine
Phenobarbital
Phentoin
L-Phenylethlamine
L-Phenylpropanolamine
Prednisolone
Prednisone
Procaine
Promazine
Promethazine
D,L-Propanolol
Propiomazine
D-Propoxyphene
D-Pseudoephedrine
Quinidine
Glucuronide
Glutethimide
Guaifenesin
Hippuric acid
Hydralazine
Hydrochlorothiazide
Hydrocodone
Hydrocortisone
Hydromorphone
O-Hydroxyhippuric acid
Ibuprofen
Imipramine
Iproniazid
(-) Isoproterenol
Isoxsuprine
Ketamine
Ketoprofen
Labetalol
Levorphanol
Lidoccaine
Loperamide
Loxapine succinate
Maprotiline
Meperidine
Mephentermine
Meprobamate
Methadone
Methaqualone
Methoxyphenamine
(±) 3,4-Methylenedioxy-methamphetamine
Methylphenidat
Methyprylon
Morphine-3-β-D-glucuronide
Nalidixic acid
Nalorphine
Naloxone
Naltrexone
Naproxen
Niacinamide
Nifedipine
Norcodein
Norethindrone
Noroxymorphone
D-Norpropoxyphene
(-) Norpseudoephedrine
Noscapine
Nylidrin
D,L-Octopamine
Oxalic acid
Oxazepam
Quinine
Rantidine
Salicylic acid
Secobarbital
Serotonin
Sulfamethazine
Sulindac
Temazepam
Tetracycline
Tetrahydrocortisone
Tetrahydrozoline
Δ^9-THC
11-nor-Δ^9-carboxy-THC
Thebaine
Thiamine
Thioridazine
D,L-Thyroxine
Tolbutamide
Tranylcypromine
Triamterene
Trifluoperazine
Trimethoprim
Trimipramine
D,L-Tryptophan
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. Hawks 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

CE

according to IVDD 98/79/ EC
MDSS
Burckhardtstrasse 1
30163 Hannover, Germany