One Step
Cocaine Test Device
Package Insert

(Catalog Number: 1185-C)

BIOMERICA

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

For professional in vitro diagnostic use only.

INTENDED USE

The One Step Cocaine Test Device is a rapid chromatographic immunoassay for the qualitative detection of cocaine metabolite, Benzoylecgonine in human urine at a cut-off concentration of 300 ng/mL.

This assay provides only a preliminary analytical test result. A more specific alternate chemical method must be used in order to obtain a confirmed analytical result. Gas chromatography/mass spectrometry (GC/MS) is the preferred confirmatory method. Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are used.

SUMMARY

Cocaine is a potent central nervous system (CNS) stimulant and a local anesthetic. Initially, it brings about extreme energy and restlessness while gradually resulting in tremors, over-sensitivity and spasms. In large amounts, cocaine causes fever, unresponsiveness, and difficulty in breathing and unconsciousness.

Cocaine is often self-administered by nasal inhalation, intravenous injection and free-base smoking. It is excreted in the urine in a short time primarily as Benzoylecgonine (1, 2). Benzoylecgonine, a major metabolite of cocaine, has a longer biological half-life (5 - 8 hours) than cocaine (0.5 - 1.5 hours), and can generally be detected for 24-48 hours after cocaine exposure (2).

The One Step Cocaine Test Device 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 cocaine metabolite in urine. The One Step Cocaine Test Device yields a positive result when the cocaine metabolite in urine exceeds 300 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 Cocaine Test Device 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. Benzoylecgonine, if present in the urine specimen below 300 ng/mL, will not saturate the binding sites of antibody in the test device. The antibody coated particles will then be captured by immobilized Benzoylecgonine conjugate and a visible colored line will appear in the test line region. The colored line will not form in the test line region if the Benzoylecgonine level exceeds 300 ng/mL because it will saturate all the binding sites of anti-Benzoylecgonine antibody.

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 proper volume of specimen has been added and membrane wicking has occurred.

REAGENTS

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

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 ready for use.
- All specimens should be considered potentially hazardous and handled in the same manner as an infectious agent.
- 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 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 before testing.

MATERIALS

Materials Provided

- Test devices
- Disposable specimen droppers
- Package insert

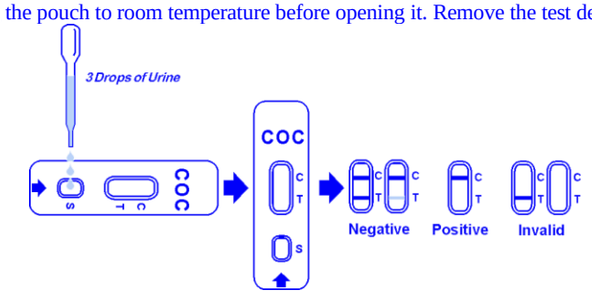
Materials Required But Not Provided

- Specimen collection container
- Timer
- External controls

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. Do not interpret the result after 10 minutes.



INTERPRETATION OF RESULTS

(Please refer to illustration above)

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 Benzoylecgonine concentration is below the detectable level (300 ng/mL).

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

POSITIVE: One red line appears in the control region (C). No line appears in the test region This positive result indicates that the Benzoylecgonine concentration is above the detectable level (300 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.

QUALITY CONTROL

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

Control standards are not supplied with this kit; however, it is recommended that positive and negative controls be tested as a good laboratory practice to confirm the test procedure and to verify proper test performance.

LIMITATIONS

1. The One Step Cocaine Test Device provides only a preliminary analytical result. A secondary quantitative analytical method must be used to obtain a confirmed result. Gas chromatography and mass spectrometry (GC/MS) are the preferred confirmatory methods (3).
2. The One Step Cocaine Test Device is a qualitative screening assay and cannot determine either the drug concentration in the urine or the level of intoxication.
3. There is a possibility that other substances and/or factors not listed above may interfere with the test and cause false results, e.g., technical or procedural errors.
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.

PERFORMANCE CHARACTERISTICS

Accuracy

A side-by-side comparison was conducted by laboratory personnel using the One Step Cocaine Test Device and a commercially available rapid test. Testing was performed on specimens previously collected from subjects presenting for Drug Screen Testing. Presumptive positive results were confirmed by GC/MS. The following results were tabulated:

Method		Other COC Rapid Test		Total Results
Biomerica One Step Test Device	Results	Positive	Negative	
	Positive	136	0	136
	Negative	7	157	164
Total Results		143	157	300
% Agreement with this commercial kit		95%	>99%	98%

When compared to GC/MS at the cut-off of 300 ng/mL, the following results were tabulated:

Method		GC/MS		Total Results
Biomerica One Step Test Device	Results	Positive	Negative	
	Positive	119	17	136
	Negative	5	159	164
Total Results		124	176	300
% Agreement with GC/MS Analysis		96%	90%	93%

Eighty (80) of these clinical samples were also run using the One Step Cocaine Test Device by an untrained operator at a different site. Based on GC/MS data, the operator obtained a statistically similar Positive Agreement, Negative Agreement and Overall Agreement rate as the laboratory personnel.

Analytical Sensitivity

A drug-free urine pool was spiked with Benzoylecgonine at the following concentrations: 0 ng/mL, 150 ng/mL, 225 ng/mL, 300 ng/mL, 375 ng/mL and 450 ng/mL. The result demonstrates 100% accuracy at 50% above and 50% below the cut-off concentration. The data are summarized below:

Benzoylecgonine Concentration (ng/mL)	Percent of Cutoff	n	Visual Result	
			Negative	Positive
0	0	30	30	0
150	-50%	30	30	0
225	-25%	30	30	0
300	Cutoff	30	9	21
375	+25%	30	7	23
450	+50%	30	0	30

Specificity

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

Compound	Concentration (ng/mL)
Benzoylecgonine	300
Cocaine HCl	780
Cocaethylene	12,500
Ecgonine HCl	32,000

Precision

A study was conducted at three geographically distinct physician's offices by untrained operators using three different lots of product to demonstrate the within run, between run and between operator precision. An identical panel of coded specimens blind labeled and tested at each site. The results are given below:

Benzoylecgonine ng/mL concentration	n	Site 1		Site 2		Site 3	
		Pos.	Neg.	Pos.	Neg.	Pos.	Neg.
0	15	0	15	0	15	0	15
150 ng/mL	15	5	10	6	8*	1	14
225 ng/mL	15	11	3*	11	4	9	6
375 ng/mL	15	15	0	15	0	13	1*
450 ng/mL	15	15	0	15	0	14	1
Non Valid	15	16/16		15/15		15/15	

*Note: Non-valid results were obtained in this treatment. Non-valid tests were provided as part of this study to ensure that readers would accurately identify non-valid test results.

Effect of Urinary Specific Gravity

Fifteen (15) urine samples of normal, high, and low specific gravity ranges were spiked with 150 ng/mL and 450 ng/mL of Benzoylecgonine respectively. The One Step Cocaine Test Device was tested in duplicate using the fifteen neat and spiked urine samples. The results demonstrate that varying ranges of urinary specific gravity does not affect the test results.

Effect of the Urinary pH

The pH of an aliquoted negative urine pool was adjusted to a pH range of 5 to 9 in 1 pH unit increments and spiked with Benzoylecgonine to 150 ng/mL and 450 ng/mL. The spiked, pH-adjusted urine was tested with the One Step Cocaine Test Device in duplicate and interpreted according to the package insert. The results demonstrate that varying ranges of pH does not interfere with the performance of the test.

Cross-Reactivity

A study was conducted to determine the cross-reactivity of the test with compounds in either drug-negative urine or Benzoylecgonine positive urine. The following compounds show no interference when tested with the One Step Cocaine Test Device at a concentration of 100 µg/mL.

Non Cross-Reacting Compounds

Acetominophen
Acetophenetidin
N-Acetylprocainamide
Acetylsalicylic acid
Aminopyrine
Amitryptyline
Amobarbital
Amoxicillin
Ampicillin
L-Ascorbic acid
DL-Amphetamine Sulfate
Apomorphine
Aspartame
Atropine
Benzilic acid
Benzoic acid
Benzphetamine
Bilirubin
(±) -Brompheniramine
Caffeine
Cannabidiol
Cannabinol
Chloralhydrate
Chloramphenicol
Chlordiazepoxide
Chlorothiazide
(±) -Chlorpheniramine
Chlorpromazine
Chlorquine
Cholesterol
Clomipramine
Clonidine
Codeine
Cortisone
(-) Cotinine
Creatinine
Deoxycorticosterone
Dextromethorphan
Diazepam
Diclofenac
Diflunisal
Digoxin
Diphenhydramine
Doxylamine
Ecgonine methylester
(-) - Ψ-Ephedrine
Erythromycin
β-Estradiol
Estrone-3-sulfate
Ethyl-p-aminobenzoate
Fenoprofen
Furosemide
Gentisic acid
Hemoglobin
Hydralazine
Hydrochlorothiazide
Hydrocodone
Hydrocortisone
O-Hydroxyhippuric acid
p-Hydroxy-methamphetamine
3-Hydroxytyramine
Ibuprofen
Imipramine
Iproniazid
(±) - Isoproterenol
Isoxsuprine
Ketamine
Ketoprofen
Labetalol
Levorphanol
Loperamide
Maprotiline
Meperidine
Meprobamate
Methadone
Methoxyphenamine
(±) -3,4-Methylenedioxy-amphetamine hydrochloride
(±) -3,4-Methylenedioxymeth-amphetamine hydrochloride
Morphine-3-β-D glucuronide
Morphine Sulfate
Nalidixic acid
Naloxone
Naltrexone
Naproxen
Niacinamide
Nifedipine
Norcodein
Norethindrone
D-Norpropoxyphene
Noscapine
DL-Octopamine
Oxalic acid
Oxazepam
Oxolinic acid
Oxycodone
Oxymetazoline
Papaverine
Penicillin-G
Pentobarbital
Perphenazine
Phencyclidine
Phenelzine
Phenobarbital
Phentermine
L-Phenylephrine
β-Phenylethylamine
Phenylpropanolamine
Prednisolone
Prednisone
Procaine
Promazine
Promethazine
DL-Propranolol
D-Propoxyphene
D-Pseudoephedrine
Quinidine
Quinine
Ranitidine
Salicylic acid
Secobarbital
Serotonin
Sulfamethazine
Sulindac
Temazepam
Tetracycline
Tetrahydrocortisone, 3-acetate
Tetrahydrocortisone 3-(β-D glucuronide)
Tetrahydrozoline
Thebaine
Thiamine
Thioridazine
DL-Tyrosine
Tolbutamide
Triamterene
Trifluoperazine
Trimethoprim
Trimipramine
Tryptamine
DL-Tryptophan
Tyramine
Uric acid
Verapamil
Zomepirac

BIBLIOGRAPHY

1. Stewart DI, T Inoba, M Ducassen, W Kalow. Clin. Pharmacol. Ther. 1979; 25:264
2. Ambre J. J. Anal. Toxicol. 1985; 9:241
3. Baselt RC. Disposition of Toxic Drugs and Chemicals in Man. 2nd Ed. Biomedical Publ., Davis, CA. 1982: 488
4. 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.,17571 Von Karman Avenue
Irvine, CA 92614 USA

EC REP

CE

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