

SureStep™ COC Cocaine Test Device (Urine) Package Insert

English

A rapid, one step test for the qualitative detection of Cocaine metabolites in human urine. For medical and other professional *in vitro* diagnostic use only.

INTENDED USE

The COC One Step Cocaine Test Device (Urine) is a rapid chromatographic immunoassay for the qualitative detection of Cocaine metabolite, Benzoyllecgonine, in human urine at a cut-off concentration of 300 ng/mL. This test will detect other related compounds, please refer to the Analytical Specificity table in this package insert.

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 Benzoyllecgonine.^{1,2} Benzoyllecgonine, 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 COC One Step Cocaine 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 Cocaine metabolite in urine. The COC One Step Cocaine Test Device (Urine) 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 COC One Step Cocaine 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. Benzoyllecgonine, if present in the urine specimen below 300 ng/mL, will not saturate the binding sites of antibody in the test. The antibody coated particles will then be captured by immobilized Benzoyllecgonine 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 Benzoyllecgonine level is above 300 ng/mL because it will saturate all the binding sites of 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 proper volume of specimen has been added and membrane wicking has occurred.

REAGENTS

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

PRECAUTIONS

- For medical and other professional *in vitro* diagnostic use only. Do not use after the expiration date.
- The test 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.
- The used test should be discarded according to local regulations.

STORAGE AND STABILITY

Store as packaged in the sealed pouch either at room temperature or refrigerated (2-30°C). The test is stable through the expiration date printed on the sealed pouch. The test 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
- Droppers
- Package insert

Materials Required But Not Provided

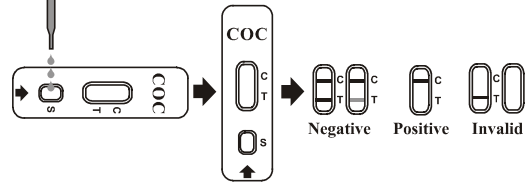
- Specimen collection container
- Timer

DIRECTIONS FOR USE

Allow test, urine specimen, and/or controls to equilibrate to room temperature (15-30°C) prior to testing.

- Bring the pouch to room temperature before opening it. Remove the test device from the sealed pouch and use it as soon as possible.
- Place the test device on a clean and level surface. Hold the dropper vertically and transfer 3 full drops of urine (approx. 100 µL) 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.
- Wait for the colored line(s) to appear. Read results at 5 minutes. Do not interpret the result after 10 minutes.

3 Drops of Urine



INTERPRETATION OF RESULTS

(Please refer to illustration above)

NEGATIVE: * Two lines appear. One colored line should be in the control line region (C), and another apparent colored line should be in the test line region (T). This negative result indicates that the Benzoyllecgonine concentration is below the detectable level (300 ng/mL).

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

POSITIVE: One colored line appears in the control line region (C). No line appears in the test line region. This positive result indicates that the Benzoyllecgonine 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. 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 colored line appearing in the control line 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 a good laboratory practice to confirm the test procedure and to verify proper test performance.

LIMITATIONS

- The COC One Step Cocaine Test Device (Urine) provides only a qualitative, preliminary analytical result. A secondary quantitative analytical method must be used to obtain a confirmed result. Gas chromatography/mass spectrometry (GC/MS) is the preferred confirmatory method.^{1,4}
- It is possible that technical or procedural errors, as well as other interfering substances in the urine specimen may cause erroneous results.
- 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.
- A positive result does not indicate level of intoxication, administration route or concentration in urine.
- 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.
- Test does not distinguish between drugs of abuse and certain medications.

PERFORMANCE CHARACTERISTICS

Accuracy

A side-by-side comparison was conducted using the COC One Step Cocaine Test Device (Urine) and a leading commercially available COC rapid test. Testing was performed on 300 clinical specimens previously collected from subjects present for Drug Screen Testing. Ten percent of the specimens employed were either at -25% or +25% level of the cut-off concentration of 300 ng/mL Benzoyllecgonine. Presumptive positive results were confirmed by GC/MS. The following results were tabulated:

Method	Other COC Rapid Test		Total Results	
	Results	Positive		Negative
COC One Step Test Device	Positive	136	0	136
	Negative	7	157	164
	Total Results	143	157	300
% Agreement	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	
	Results	Positive		Negative
COC One Step Test Device	Positive	119	17	136
	Negative	5	159	164
	Total Results	124	176	300
% Agreement	96%	90%	93%	

Analytical Sensitivity

A drug-free urine pool was spiked with Benzoyllecgonine 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 >99% accuracy at 50% above and 50% below the cut-off concentration. The data are summarized below:

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

Analytical Specificity

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

Compound	Concentration (ng/mL)
Benzoyllecgonine	300
Cocaine HCl	780
Cocacetyllecgonine	12,500
Egonine HCl	32,000

Precision

A study was conducted at three physicians' 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 containing, according to GC/MS, no Benzoyllecgonine, 25% Benzoyllecgonine above and below the cut-off and 50% Benzoyllecgonine above and below the 300 ng/mL cut-off was provided to each site. The following results were tabulated:

Benzoyllecgonine Concentration (ng/mL)	n per Site	Site A		Site B		Site C	
		Pos.	Neg.	Pos.	Neg.	Pos.	Neg.
0	15	0	15	0	15	0	15
150	15	5	10	6	8*	1	14
225	15	1	3*	11	4	9	6
375	15	15	0	15	0	13	1*
450	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 urine specimens of normal, high, and low specific gravity ranges were spiked with 150 ng/mL and 450 ng/mL of Benzoyllecgonine. The COC One Step Cocaine Test Device (Urine) was tested in duplicate using the fifteen neat and spiked urine specimens. The results demonstrate that varying ranges of urinary specific gravity do not affect the test results.

Effect of 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 Benzoyllecgonine to 150 ng/mL and 450 ng/mL. The spiked, pH-adjusted urine was tested with the COC One Step Cocaine Test Device (Urine) in duplicate. The results demonstrate that varying ranges of pH do 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 Benzoyllecgonine positive urine. The following compounds show no interference when tested with the COC One Step Cocaine Test Device (Urine) at a concentration of 100 µg/mL.

Non Cross-Reacting Compounds

Acetaminophen	Diazepam	Methadone	Prednisone
Acetophenetidin	Diclofenac	Methoxyphenamine	Procaine
N-Acetylprocainamide	Diffusal	(±)-3,4-Methylenedioxyamphetamine	Promazine
Acetylsalicylic acid	Digoxin	D.L.-Propranolol	Promethazine
Aminopyrine	Diphenhydramine	D.L.-Propranolol	D-Pseudoephedrine
Amiripyline	Doxylamine	Morphine-3-β-D-glucuronide	Quinidine
Amobarbital	Egonine methyl ester	Morphine-3-β-D-glucuronide	Quinine
Amoxicillin	(-)-Epinephrine	Quinine	Ranitidine
Ampicillin	Erythromycin	Salicylic acid	Secobarbital
L-Ascorbic acid	β-Estradiol	Nalidixic acid	Serotonin
D,L-Amphetamine sulfate	Estrone-3-sulfate	Naloxone	Sulfamethazine
Apomorphine	Ethyl-p-aminobenzoate	Naltrexone	Sulfamethazine
Aspartame	Fenpropfen	Naproxen	Sulindac
Atropine	Furosemide	Niacinamide	Tamoxifen
Benzilic acid	Genisteic acid	Nifedipine	Tetrazepam
Benzoic acid	Hemoglobin	Norcodeine	Tetracycline
Benzphetamine	Hydralazine	Nortriptyline	Tetrahydrocortisone
Bilirubin	Hydrochlorothiazide	D-Norpropoxyphene	3-Acetate
(±)-Brompheniramine	Hydrocodone	Noscapine	Tetrahydrocortisone
Caffeine	Hydrocortisone	D,L-Octopamine	3-(β-D-glucuronide)
Cannabidiol	O-Hydroxyhippuric acid	Oxalic acid	Tetrahydrozoline
Cannabinol	p-Hydroxy-methamphetamine	Oxazepam	Thebaine
Chloralhydrate	3-Hydroxytyramine	Oxycodone	Thiamine
Chlorpheniramine	Ibuprofen	Oxymetazoline	Thioridazine
Chloridiazepoxide	Imipramine	Papaverine	D,L-Tyrosine
Chlorothiazide	Iproniazid	Penicillin-G	Tobutamide
(±)-Chlorpheniramine	Isoproterenol	Pentobarbital	Triamterene
Chlorpromazine	Isosuxiprine	Perphenazine	Trifluoperazine
Chlorquine	Ketamine	Phencyclidine	Trimethoprim
Cholesterol	Ketoprofen	Phenelzine	Trimipramine
Clomipramine	Labetalol	Phenobarbital	Tryptamine
Clonidine	Lorazepam	Phentermine	D,L-Tryptophan
Cocaine	(-) Cotinine	L-Phenylephrine	Tyramine
Cortisone	Maprotiline	β-Phenylethylamine	Uric acid
(-) Cotinine	Meperidine	Phenylpropanolamine	Verapamil
Creatinine	Dextroxylocosterone	Prednisolone	Zomepirac
Dextromethorphan			

BIBLIOGRAPHY

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- Ambré J.J. Anal. Toxicol. 1985; 9:241
- Baselt RC. Disposition of Toxic Drugs and Chemicals in Man, 2nd Ed. Biomedical Publ., Davis, CA. 1982: 488
- Hawks RL, CN Chiang. Urine Testing for Drugs of Abuse. National Institute for Drug Abuse (NIDA), Research Monograph 73, 1986

Index of Symbols

	Attention, see instructions for use		Tests per kit		Authorized Representative
	For <i>in vitro</i> diagnostic use only		Use by		Do not reuse
	Store between 2-30°C		Lot Number		Catalog #

Manufacturer

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