



# COC Rapid Test Cassette (Urine)

## Package Insert

REF DCO-102 English

A rapid test for the qualitative detection of Cocaine metabolite in human urine. For professional *in vitro* diagnostic use only.

### INTENDED USE

The COC Rapid Test Cassette 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 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.<sup>1,2</sup> 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.<sup>2</sup> The COC (Cocaine) Test Cassette 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 Rapid Test Cassette yields a positive result when the Cocaine metabolite in urine exceeds 300ng/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 Rapid Test Cassette 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 300ng/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 300ng/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

Please read all the information in this package insert before performing the test.

- For medical and other professional *in vitro* diagnostic use only. Do not use after the exp. date.
- The test 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 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 clean and dry container. Urine collected at any time of the day may be used. Urine specimens exhibiting visible particles should be centrifuged, filtered, or allowed to settle to obtain a clear specimen for testing.

#### Specimen Collection

Urine specimens may be stored at 2-8°C for up to 48 hours prior to assay. For long-term storage, specimens may be frozen and stored below -20°C. Frozen specimens should be thawed and mixed before testing.

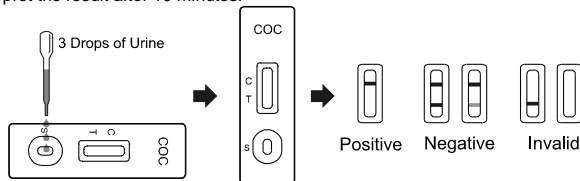
### MATERIALS PROVIDED

- Test Cassettes
- Material provided
  - Droppers
  - Package Insert
- Materials required but not provided
  - Specimen Collection Containers
  - Timer

### DIRECTIONS FOR USE

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

- Bring the pouch to room temperature before opening it. Remove the cassette from the sealed pouch and use it within one hour.
- Place the cassette on a clean and level surface. Hold the dropper vertically and transfer 3 full drops of urine (approx. 120µL) to the specimen well of the cassette, and then start the timer. Avoid trapping air bubbles in the specimen well. See illustration below.
- Wait for the colored 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 the illustration above)

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

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

**POSITIVE:** One colored line appears in the control region (C). No line appears in the test region (T). This positive result indicates that the Benzoyllecgonine concentration is above the detectable level of 300ng/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 with a new test cassette. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

### QUALITY CONTROL

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

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

### LIMITATIONS

- The COC Rapid Test Cassette provides only a qualitative, preliminary result. A secondary analytical method must be used to obtain a confirmed result. Gas chromatography/mass spectrophotometry (GC/MS) is the preferred confirmatory method.<sup>1,2</sup>
- 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 indicates presence of the drug or its metabolites but 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 Rapid Test Cassette and a commercially available COC rapid test. Testing was performed on 100 clinical specimens previously collected from subjects present for Drug Screen Testing. The following results were tabulated:

Method	Other COC Rapid Test		Total Results
	Positive	Negative	
COC Rapid Test Cassette	Positive	0	40
	Negative	0	60
	<b>Total Results</b>	40	60
<b>% Agreement</b>	>99.9%	>99.9%	>99.9%

A side-by-side comparison was conducted using the COC Rapid Test Cassette and GC/MS at the cut-off of 300ng/mL. Testing was performed on 250 clinical specimens previously collected from subjects present for Drug Screen Testing. The following results were tabulated:

Method	Results	GC/MS		Total Results
		Positive	Negative	
COC Rapid Test Cassette	Positive	111	3	114
	Negative	2	134	136
	<b>Total Results</b>	113	137	250
<b>% Agreement</b>		98.2%	97.8%	98.0%

### Analytical Specificity

The following table lists compounds that are positively detected in urine by the COC Rapid Test Cassette at 5 minutes.

Compound	Concentration(ng/mL)	Compound	Concentration(ng/mL)
Benzoyllecgonine	300	Cocaehtylene	20,000
Cocaine HCl	200	Ecgonine HCl	30,000

### Analytical Sensitivity

A drug-free urine pool was spiked with Benzoyllecgonine at the following concentrations: 0ng/mL, 150ng/mL, 225ng/mL, 300ng/mL, 375ng/mL, 450ng/mL and 900ng/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)	Cut-off	n	Visual Results	
			-	+
0	0	30	30	0
150	-50%	30	30	0
225	-25%	30	26	4
300	Cut-off	30	13	17
375	+25%	30	3	27
450	+50%	30	0	30
900	3x	30	0	30

### Precision

A study was conducted at three hospitals 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 results are given below:

Benzoyllecgonine Concentration(ng/mL)	n	Site A		Site B		Site C	
		-	+	-	+	-	+
0	10	10	0	10	0	10	0
150	10	10	0	10	0	10	0
225	10	9	1	9	1	9	1
375	10	1	9	1	9	1	9
450	10	0	10	0	10	0	10

### Effect of Urinary Specific Gravity

Fifteen urine specimens of normal, high and low specific gravity ranges were spiked with 150ng/mL and 450ng/mL of Benzoyllecgonine. The COC Rapid Test Cassette 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 150ng/mL and 450ng/mL. The spiked, pH-adjusted urine was tested with the COC Rapid Test Cassette 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-free urine or Benzoyllecgonine positive urine. The following compounds show no cross-reactivity when tested with COC Rapid Test Cassette at a concentration of 100µg/mL.

### Non Cross-Reacting Compounds













Acetaminophen	Diazepam	Methadone	Prednisone
Acetophenetidin	Diclofenac	Methoxyphenamine	Procaine
N-Acetylprocainamide	Diflunisal	(±)-3,4-Methylenedioxy-amphetamine	Promazine
Acetylsalicylic acid	Digoxin	(±)-3,4-Methylenedioxy-methamphetamine	Promethazine
Aminopyrine	Diphenhydramine	Morphine-3-β-D-glucuronide	D-Propranolol
Amitypytline	Doxylamine	Morphine Sulfate	D-Pseudoephedrine
Amobarbital	Ecgonine methylester	β-Estradiol	Quinidine
Amoxicillin	(-)-ψ-Ephedrine	Nalidixic acid	Quinine
Ampicillin	Erythromycin	Estrone-3-sulfate	Ranitidine
L-Ascorbic acid	β-Estradiol	Naloxone	Salicylic acid
D,L-Amphetamine sulfate	Estrone-3-sulfate	Naltrexone	Secobarbital
Apomorphine	Ethyl-p-aminobenzoate		

Aspartame	Fenopfen	Naproxen	Serotonin
Atropine	Furosemide	Niacinamide	Sulfamethazine
Benzilic acid	Gentisic acid	Nifedipine	Sulindac
Benzoic acid	Hemoglobin	Norcodein	Temazepam
Benzphetamine	Hydralazine	Norethindrone	Tetracycline
Bilirubin	Hydrochlorothiazide	D-Norpropoxyphene	Tetrahydrocortisone,
(±) -Brompheniramine	Hydrocodone	Noscapine	3-Acetate
Caffeine	Hydrocortisone	D,L-Octopamine	Tetrahydrocortisone
Cannabidiol	O-Hydroxyhippuric acid	Oxalic acid	3-(β-D glucuronide)
Cannabinol	p-Hydroxy-	Oxazepam	Tetrahydrozoline
Chloralhydrate	methamphetamine	Oxolinic acid	Thebaine
Chloramphenicol	3-Hydroxytyramine	Oxycodone	Thiamine
Chlordiazepoxide	Ibuprofen	Oxymetazoline	Thioridazine
Chlorothiazide	Imipramine	Papaverine	D,L-Tyrosine
(±) -Chlorpheniramine	Iproniazid	Penicillin-G	Tolbutamide
Chlorpromazine	(±) - Isoproterenol	Pentobarbital	Triamterene
Chlorquine	Isoxsuprine	Perphenazine	Trifluoperazine
Cholesterol	Ketamine	Phencyclidine	Trimethoprim
Clomipramine	Ketoprofen	Phenelzine	Trimipramine
Clonidine	Labetalol	Phenobarbital	Tryptamine
Codeine	Levorphanol	Phentermine	D,L-Tryptophan
Cortisone	Loperamide	L-Phenylephrine	Tyramine
(-) Cotinine	Maprotiline	β-Phenylethylamine	Uric acid
Creatinine	Meperidine	Phenylpropanolamine	Verapamil
Deoxycorticosterone	Meprobamate	Prednisolone	Zomepirac
Dextromethorphan			

**【BIBLIOGRAPHY】**

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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

**Index of Symbols**

	Consult instructions for use or consult electronic instructions for use		Contains sufficient for <n> tests		Temperature limit
	In vitro diagnostic medical device		Batch code		Catalogue number
	Authorized representative in the European Community/European Union		Use-by date		Do not re-use
	Do not use if package is damaged and consult instructions for use		Manufacturer		Caution

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