COC Rapid Test Cassette (Urine)
Package Insert

AL04-04-122 | 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, Benzoylecgonine, 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 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 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. Benzoylecgonine, 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 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 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-Benzoylecgonine antibody-coupled particles and Benzoylecgonine-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】

Material provided

- Test cassettes
- Droppers
- Package insert

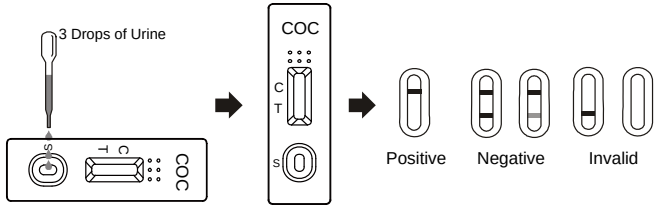
Materials required but not provided

- Specimen collection container
- Timer

【DIRECTIONS FOR USE】

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

1. Bring the pouch to room temperature before opening it. Remove the cassette from the sealed pouch and use it within one hour.
2. 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.
3. Wait for the color 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 lines appear. One color line should be in the control region (C), and another apparent color line should be in the test region (T). This negative result indicates that the Benzoylecgonine 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 color line appears in the control region (C). No line appears in the test region (T). This positive result indicates that the Benzoylecgonine 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 Cassette immediately and contact your local distributor.

【QUALITY CONTROL】

A procedural control is included in the test. A color 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 Cassette; 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】

1. The COC Rapid Test Cassette provides only a qualitative, preliminary analytical result. A secondary analytical method must be used to obtain a confirmed result. Gas chromatography/mass spectrophotometry (GC/MS) is the preferred confirmatory method. [1,2]
2. It is possible that technical or procedural errors, as well as other interfering substances in the urine specimen may cause erroneous results.
3. 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.
4. A positive result indicates presence of the drug or its metabolites but does not indicate level of intoxication, administration route or concentration in urine.
5. 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.
6. Test does not distinguish between drugs of abuse and certain medications.

【EXPECTED VALUES】

This negative result indicates that the Benzoylecgonine concentration is below the detectable level of 300ng/ml. Positive result means the concentration of Benzoylecgonine is above the level of 300ng/ml. The COC Rapid Test Cassette has a sensitivity of 300ng/ml

【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
COC Rapid Test Cassette	Results	Positive	Negative	
	Positive	40	0	40
	Negative	0	60	60
Total Results		40	60	100
% Agreement		>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		GC/MS		Total Results
COC Rapid Test Cassette	Results	Positive	Negative	
	Positive	111	3	114
	Negative	2	134	136
Total Results		113	137	250
% Agreement		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)
Benzoylecgonine	300	Cocaethylene	20,000
Cocaine HCl	200	Ecgonine HCl	30,000

Analytical Sensitivity

A drug-free urine pool was spiked with Benzoylecgonine 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:

Benzoylecgonine Concentration(ng/ml)	Cut-off	n	Visual Result	
			-	+
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	3×	30	0	30

Precision

A study was conducted at three hospitals by laypersons 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 Benzoylecgonine, 25% Benzoylecgonine above and below the cut-off, and 50% Benzoylecgonine above and below the 300 ng/mL cut-off was provided to each site. The results are given below:

Benzoylecgonine 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 Benzoylecgonine. 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 Benzoylecgonine 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 Benzoylecgonine 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

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

【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),Res earch Monograph 73, 1986

Index of Symbols

	Attention, see instructions for use	Σ	Tests per kit	EC REP	Authorized Representative
IVD	For in vitro diagnostic use only		Use by	2	Do not reuse
2°C – 30°C	Store between 2-30°C	LOT	Lot Number	REF	Catalog #
	Do not use if package is damaged				

Hangzhou AllTest Biotech Co., Ltd.
#550, Yinhai Street
Hangzhou Economic & Technological Development Area
Hangzhou - 310018, P. R. China
www.alltests.com.cn

EC REP
MedNet GmbH
Borkstrasse 10
48163 Muenster
Germany

Distributed by :

PT. TRIMITRA DIAGNOSTIK INDONESIA
Jl. Pangeran Jayakarta, Rukan Buntu Warga No. 23A
Mangga Dua Selatan - Sawah Besar, DKI Jakarta 10730
Email : info@tdi.co.id

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