DRG Rapid Cocaine Test (RAP-3325)

FOR THE QUALITATIVE ASSESSMENT OF COCAINE METABOLITES IN HUMAN URINE.
For in vitro Diagnostic and Forensic Use

INTENDED USE

The RapidCOC test is an immunochromatography based one step in vitro test. It is designed for qualitative determination of Cocaine's metabolite, benzoylecgonine in human urine specimens above a cut-off level of 300 ng/ml. This assay has not been evaluated in the point of care location and is for use by Healthcare Professionals only.
This assay provides only a preliminary analytical test result. A more specific alternative chemical method must be used in order to obtain a confirmed analytical result. Gas chromatography/ mass spectrometry (GC/MS) has been established as the preferred confirmatory method by the Substance Abuse Mental Health Services Administration (SAMHSA). Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are indicated.

SUMMARY AND EXPLANATION

Derived from the leaves of cocoa plant, cocaine is a potent central nervous system stimulant as well as a local anesthetic. Some of the psychological effects induced by cocaine are: euphoria, confidence and a sense of increased energy, accompanied by increased heart rate, dilation of the pupils, fever, tremors and sweating. Continued ingestion of cocaine could induce tolerances and physiological dependency which leads to its abuse. Cocaine is used by smoking, intravenous, intranasal or oral administration and excreted in the urine primarily as benzoylecgonine in a short period.
Benzoylecgonine has a biological half-life of 5 - 8 hours, which is much longer than that of cocaine (0.5 - 1.5 hours), and can be generally detected for 12 - 72 hours after cocaine use or exposure. However, the length of time following drug use for which a positive result may occur is dependent upon several factors, including the frequency and amount of drug, metabolic rate, excretion rate, drug half-life, and the drug user's age, weight, activity, and diet.

TEST PRINCIPLE

The RapidCOC test is based on the principle of specific immunochemical reaction between antibodies and antigens to analyze particular compounds in human urine specimen. The assay relies on the competition for binding antibody between drug conjugate and free drug which may be present in the urine specimen being tested. When drug is present in the urine specimen, it competes with drug conjugate for the limited amount of antibody-dye conjugate. When the amount of drug is equal or more than the cut-off, 300 ng/ml, it will prevent the binding of drug conjugate to the antibody. Therefore, a positive urine specimen will not show a colored band on the test line zone, indicating a positive result, while the presence of a colored band indicates a negative result.
A control line is present in the test window to work as procedural control. This colored band should always appear on the control line zone if the test device is stored in good condition and the test is performed appropriately.

MATERIALS PROVIDED

1. Instructions for use.
2. Rapid COC test device. The amount of each coated antigen and/or antibody on the strip is less than 1.0 mg for antigen conjugate and is less than 1.0 mg for goat anti-mouse IgG antibody.
   Test zone: contains benzoylecgonine bovine protein antigen conjugates.
   Control zone: contains Goat anti-mouse IgG antibody.
   Conjugate pad: contains mice monoclonal anti-benzoylecgonine antibody.

MATERIALS REQUIRED BUT NOT PROVIDED

1. Urine collection container.
2. Timer or clock.

STORAGE AND STABILITY

The test device should be stored at 2 to 30^{o}C and will be effective until the expiration date stated on the package. The product is humidity-sensitive and should be used immediately after being open. Any improperly sealed product should be discarded.

PRECAUTIONS

1. For in vitro diagnostic and forensic use only.
2. Do not use the product beyond the expiration date.
3. Handle all specimens as potentially infectious.
4. Humidity sensitive product, do not open foil pouch until it is ready to be tested.
5. Use a new urine specimen cup for each sample to avoid cross contamination.

SPECIMEN COLLECTION AND PREPARATION

It is required that approximately 150 µl of sample for each test. Fresh urine specimens do not need any special handling or treatment. Specimens should be collected in a clean, dry, plastic or glass container. If the assay is not performed immediately, urine specimen may be refrigerated at 2-8^{o}C or frozen up to 7 days. Specimens should be thawed and brought to room temperature before testing. Urine specimens exhibiting a large amount of precipitate or turbidity should be centrifuged or allowed to settle before testing. Avoid contact with skin by wearing gloves and proper laboratory attire.

QUALITY CONTROL

Good Laboratory practice recommends the daily use of control materials to validate the reliability of device. Control materials should be assayed as clinical specimen and challenging to the assay cutoff concentration, e.g., 25% above and below cutoff concentration. If control values do not fall within establish range, assay results are invalid. Control materials which is not provided with this test kit are commercially available.

The Rapid Drugs of Abuse Test provides a built-in process control with a different antigen/antibody reaction at the control region ©. This control line should always appear regardless the presence of drug or metabolite. If the control line does not appear, the test device should be discarded and the obtained result is invalid. The presence of this control band in the control region serve as 1) verification that sufficient volume is added, 2) that proper flow is obtained.

PROCEDURE

1. Bring all materials and specimens to room temperature.
2. Remove the test strip from the sealed foil pouch.
3. Dip the strip into the urine specimen with the arrow pointing toward the sample. The sample level should not be higher than the arrow pointed maximum line.
4. Hold the strip in the urine until a reddish color appears at the test area (approximately 20 seconds).
5. Withdraw the strip and place it face up on a clean, non-absorptive surface or leave the strip in urine if the urine level is not higher than arrow pointed maximum line
6. Read the results at 5 minutes after adding the sample.
   Do not interpret the result after 5 minutes.

INTERPRETATION OF RESULTS

Negative:

Two colored bands form. The appearance of two colored bands, one in test line zone and the other in control line zone, indicates negative results. The negative result indicates that the Cocaine concentration in the specimen is either zero or less than cut-off level.

Positive:

One colored band forms. One colored band appears in control line zone. No colored band is found in test line zone. This is an indication that the Cocaine level in the specimen is above the cut-off level.

Invalid:

If there is no colored band in control line zone, the test result is invalid. Retest the sample with a new device.

Note: A borderline (+/-) in test line region zone be considered negative result.

LIMITATION OF PROCEDURE

The assay is designed for use with human urine only. A positive result with any of the tests indicates only the presence of a drug/metabolite and does not indicate or measure intoxication.

There is a possibility that technical or procedural error as well other substances in certain foods and medicines may interfere with the test and cause false results. Please refer to the "SPECIFICITY" section for lists of substances that will produce either positive results, or that do not interfere with test performance. If a drug/metabolite is found present in the urine specimen, the assay does not indicate frequency of drug use or distinguish between drug of abuse and certain foods and medicines.

EXPECTED RESULTS

The RapidCOC Test is a qualitative assay. It identifies benzoylecgonine in human urine at a concentration of 300 ng/ml or higher. The concentration of the benzoylecgonine cannot be determined by this assay. The test is intended to distinguish negative result from presumptive positive result. All positive results must be confirmed using an alternate method, preferably GC/MS.

PERFORMANCE CHARACTERISTICS

A. Accuracy

The accuracy of the RapidCOC test was evaluated in comparison to GC/MS at a cut-off of 300 ng/ml of benzoylecgonine. One hundred and two urine specimens with GC/MS confirmed benzoylecgonine concentrations were evaluated in this study. The results are summarized and presented below:

	(-)		(+)		
RapidCOC Test	Negative By GC/MS	Near cutoff negative (between -25% and c/o	Near cutoff positive (between c/o and +25%	GC/MS Positive (greater than +25%)	Percent agreement with GC/MS
Positive	0	2	3	45	96.0
Negative	46	5	0	1	98.1
Total	46	7	3	46	

Positive % agreement: 96.0, Negative % agreement: 98.1. Three specimens were found discrepant between the RapidCOC and GC/MS method. When compared those data, 100% (3 out of 3) of the discrepancy specimens were found between -25% and +25% cut-off concentration (225 - 375 ng/ml).

B. Sensitivity

The cut-off concentration (sensitivity level) of RapidCOC test is determined to be 300ng/ml.

C. Precision

The precision study was performed by three individuals observing the test result to determine the random error of visual interpretation. The test results were found to have no significant differences between the three observers.

Device	Control Con.	No. of	No. of positive			No. of borderline #			No. of negative		
	ng/ml	Tested	1*	2*	3*	1*	2*	3*	1*	2*	3*
	150	40							42	42	42
	225	40				37	37	37	3	3	3
COC	300	40	19	19	19	21	21	21			
	375	40	39	39	39	1	1	1			
	450	40	40	40	40						

D. Specificity

The specificity for RapidCOC test was tested by adding various drugs, drug metabolites, and other compounds that are likely to be present in urine. All compounds were prepared in drug-free normal human urine.

1. Interference testing

The RapidCOC test performance at cut-off level is not affected when pH and Specific Gravity ranges of urine specimen are at 4.0 to 9.0 and 1.005 to 1.035.

The following substances were tested and confirmed not to interfere with RapidCOC test at the listed concentrations:

Glucose	2000 mg/dl	Human albumin	2000 mg/dl
Human hemoglobin	10 mg/dl	Urea	4000 mg/dl
Uric acid	10 mg/dl		

2. Specificity

The following table lists compounds that are detected by RapidCOC test which produced positive results when tested at levels equal or greater than the concentrations listed below:

Compounds	**Con. (ng/ml)**	**Compounds**	**Con. (ng/ml)**
Benzoylecgonine	300	Cocaine	30,000

Each listed substance that commonly found in the urine was evaluated and indicated negative result at concentration of 100 µg/ml.

Acetaminophen	4-Acetamidophenol	Acetylsalicylic acid	Amikacin
Amitriptyline	Amobarbital	Arterenol	Aspartame
Ascorbic acid	Atrophine	Caffeine	Camphor
Chloroquine	Chlopheniramine	Cortisone	Deoxyephedrine
Dextromethorphan	Digitoxin	Digoxin	Diphenhydramine
Ecgonine	Ecgonine methyl ester	Ephedrine	Epinephrine
Gentisic	Guaiacol glycer ester	Histamine	Hydrochlorothiazide
Homatrophine	Imipramine	Ibuprofen	Isoproterenol
Ketamine	Lidocaine	Meperidine	Methadone
Methaqualone	Methylphenidate	Neomycin	Niacinamide
Perphenazine	Penicillin G	Phenylethylamine-α	Phenylpropanolamine
Promethazine	Pseudoephedrine	Quinine antidine	Salicyclic
Tetracycline	Tetrahydrozoline	Theophyline	Thioridazine
Trifluoperazine	Tryptophan	Tyramine	

REFERENCES

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