

Cocaine (COC) cassette / strip test (urine)

For in vitro diagnostic use only



Cat. No. **1-313-K040**

Cocaine (COC) cassette: 40 tests

Cat. No. **1-313-P050**

Cocaine (COC) strips: 50 tests

INTENDED USE

Cocaine (COC) test is a rapid, qualitative immunoassay for the determination of benzoylecgonine, the major metabolite of cocaine in human urine. The test is used to screen urine for the presence of the benzoylecgonine at a cut off concentration of 300 ng/ml. The test is for use by health care professionals only.

This test 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 spectrophotometry (GC/MS) is the preferred confirmatory method. Clinical considerations and professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are indicated.

SUMMARY

Cocaine is derived from the leaves of the cocoa plant and 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 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 lead to its abuse. Cocaine is rapidly absorbed, almost completely metabolized by the liver and excreted in the urine as benzoylecgonine. Benzoylecgonine has a biological half-life of 5 to 8 hours, which is much longer than that of cocaine (0.5 to 1.5 hours), and can be generally detected 12-72 hours after cocaine use or exposure. The Cocaine (COC) test detects benzoylecgonine in urine at concentrations of 300 ng/mL and greater as recommended by SAMSHA (NIDA). The test is a qualitative, visual screening immunoassay. The method employs unique antibodies to selectively identify the drug in the test urine with a high degree of sensitivity and specificity.

TEST PRINCIPLE

The test device consists of a chromatographic absorbent device in which the drug or drug metabolites in the sample compete with a drug conjugate immobilized on a porous membrane support for the limited antibody sites. As the test sample flows up through the absorbent device, the labeled antibody-dye conjugate binds to the free drug in the specimen forming an antibody-antigen complex. This complex competes with immobilized antigen conjugate in the positive reaction zone and will not produce a magenta color band when the drug is above the detection level suggested for the immunoassay method. Unbound dye conjugate binds to the reagent in the negative control zone, producing a magenta color band, demonstrating that the reagents and device are functioning correctly.

A **negative** specimen produces two (2) distinct color bands, one in the test area and one in the control region. A **positive** specimen produces only one (1) color band in the control region.

MATERIALS PROVIDED

	1-313-K040	1-313-P050
Cocaine (COC) cassettes	40 pcs	---
Cocaine (COC) strips	---	50 pcs
Instruction for use	1 pc	1 pc

OTHER MATERIALS AND EQUIPMENT

(not included in the kit)

- Specimen container
- Timer
- Positive and negative urine controls

STORAGE AND STABILITY

The test device can be stored at 2-30°C and will be stable until the expiration date. Do not use after the expiration date.

SAMPLE COLLECTION

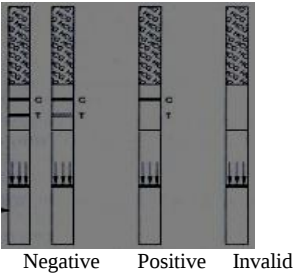
Collect 10 ml of urine into a clean, dry, plastic or glass container that does not contain preservative. Some plastics may adsorb drugs. If not tested immediately, urine specimens may be stored refrigerated at 2-8°C for up to 7 days and then frozen (-20°C or colder) prior to assaying. Refrigerated or frozen samples must be warmed to room temperature and gently mixed before testing. Urine samples exhibiting visible precipitates or turbidity should be centrifuged or allowed to settle so a clear aliquot may be sampled for this assay. Collection of samples may

require mandatory procedures and custody and control records. Poppy seed ingestion has been associated with positive test results in some samples.

TEST PROCEDURE

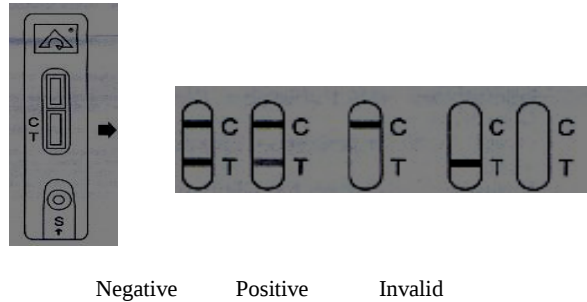
For strip test:

- 1. Bring all materials and specimens to room temperature.
- 2. Remove test strip from the sealed foil pouch.
- 3. Dip the test strip into the urine sample with the arrows pointing toward the specimen.
- 4. The urine level should reach the maximum line marked on the strip, but must not exceed the maximum line.
- 5. Hold the strip in the urine until a reddish color appears at the lower edge of the test membrane (approximately 10 seconds).
- 6. Withdraw the strip and place it face up on a clean, dry surface.
- 7. Read the results between 3-8 minutes after adding the sample.



For cassette test:

- 1. Bring all materials and specimens to room temperature.
- 2. Remove test card from the sealed foil pouch.
- 3. Place the test card on a flat dry surface.
- 4. Using the provided plastic dropper, dispense 3 drops of urine sample to the sample well of the test card. Start timing.
- 5. Read the results between 3-8 minutes after adding the sample.



INTERPRETATION OF RESULTS

Read test results between 3-8 minutes. **Do not interpret results after 8 minutes.**

NEGATIVE Two (2) pink/purple bands form. In addition to the control band, a pink/purple band also appears in the test region.

Note: This immunoassay is a screening test. A negative result indicates the drug level is below the detection sensitivity. It is important to understand that concentrations of the drug below cut off may cause a faint "ghost line" to form in the test region. This "ghost line" should be considered a negative result.

POSITIVE One (1) pink/purple band appears in the control region. No band is found in the test region. This is an indication that the drug level is above the detection sensitivity level.

INVALID If there is no pink/purple band in the control area of the strip, the test result is invalid. Retest the sample using a new device.

Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly when preliminary results are positive. Positive results should be confirmed by an alternate method such as GC/MS.

EXPECTED VALUES

The Cocaine (COC) test identifies benzoylecgonine in human urine at a cut off concentration of 300 ng/mL. The concentration of the drug can not be determined using this test. The test is intended to screen urine to separate a negative result from a presumptive positive result. All positive results must be confirmed using an alternate method, preferably GC/MS.

QUALITY CONTROL

- 1. Each test device has a control band to indicate that the sample volume and migration is adequate, and that the colloidal gold is dissolving as expected. An invalid result must be repeated using a new test device.
- 2. Positive and negative, drug free urine controls can be used to validate reagent performance and establish test reliability. Commercial drug urine controls are available, but not provided with this test. NIDA recommended guidelines for drugs of abuse screening indicate controls should contain the drug at a level at least 20% above the NIDA cutoff value. If control values do not fall within the established limits, assay results are invalid.

PERFORMANCE CHARACTERISTICS

Accuracy:

A comparative evaluation of 100 clinical urine specimens was performed using the Cocaine (COC) test and a commercially available EIA screen/semi quantitative test. Both tests have a cut off concentration of 300 ng/mL benzoylecgonine (Table 1). The drug concentration of samples covered the entire assay range and included 20 samples around the cut off concentration. The accuracy of the Cocaine (COC) test was 88%. All results were confirmed with GC/MS benzoylecgonine testing. The twelve discrepant results were between 272-471 ng/ml of benzoylecgonine. Comparison summary:

	result	Commercial EIA test		total
		positive	negative	
Cocaine (COC) test	positive	48	12	60
	negative	0	40	40
total		48	52	100

Precision:

Three lots of Cocaine (COC) test were assayed using urine controls containing 0 ng/mL, 236 ng/mL, 316 ng/mL and 472 ng/mL benzoylecgonine for 20 days. Three individuals read the results independently. A correct positive result was obtained by all individuals, 100% of the time with the 316 ng/ml and the 472 ng/ml concentrations. A correct negative result was found by all individuals, 100% of the time with the 0 ng/ml concentration. The 236 ng/ml level varied somewhat depending on the experience of the observer. The inexperienced observer reported this level as positive 100% of the time, while the two experienced readers reported negative results 100% of the time.

Sensitivity:

Different concentrations of benzoylecgonine were tested and results are summarized below. Some users may find variable results up to +/- 35% of the Cocaine (COC) test cut off. GC/MS testing must be performed to confirm results. Benzoylecgonine conc. (ng/ml) - #Tested/#Results
0 ng/mL – 25/25 Negative
150 ng/mL – 25/25 Negative
300 ng/mL – 25/25 Positive
375 ng/mL – 25/25 Positive

Specificity and interfering substances

Compounds yielding a positive reaction:

Cocaine	15,000 ng/ml
Ecgonine	100,000 ng/ml
Tropacocaine	100,000 ng/ml

The following compounds did not interfere:

Glucose	2000 mg/dl
Uric Acid	10 mg/dl
Human Albumin	2000 mg/dl
Urea	4000 mg/dl
Hemoglobin	10 mg/dl
Bilirubin	2 mg/dl

Compounds that give negative results at concentrations up to 100 ng/ml (unless noted):

4-Acetamidophenol	Acetylsalicylic Acid
Amikacin ethyl-p-aminobenzoate	Amitriptyline
Amphetamine	Arterenol
Aspartame	Atropine
Caffeine	Camphor
Chloroquine	Chlorpheniramine
Cortisone	Deoxyepinephrine
Dextromethorphan	Digitoxin
Digoxin	Epinephrine
Meperidine (200 µg/mL)	Methadone
d,l,Methamphetamine	d, Methamphetamine
Morphine	Naloxone
Neomycin	Niacinamide
11-Nor- 8-THC-9-COOH (10 µg/mL)	
11-Nor-9 THC-9-COOH (10 µg/mL)	
Oxazepam	Perphenazine
Phencyclidine	Phenobarbital
Phenylethylamine 5.5-diphenylhydantoin	
Phenylpropanolamine	Procaine
Ephedrine	Gentisic Acid
Guaiacol glyceryl ether	Histamine
Homatropine	Imipramine
Isoproterenol	Ketamine
Lidocaine	Pseudoephedrine
Rantidine	Salicylic Acid
Secobarbital	Tetracycline
Tetrahydrozoline	Theophylline
Thioridazine	Trifluoperazine
Promethazine	

LIMITATIONS OF THE TEST

1. This product is designed to be used for the detection of benzoylecgonine in human urine only.
2. Although the Cocaine (COC) test is very accurate in detecting cocaine metabolites in urine, there is a possibility of false results due to the presence of interfering substances.
3. The test is a qualitative screening assay and is not suggested for determining the quantitative cocaine level of urine.
4. Adulterants, such as bleach or other strong oxidizing agents, when added to urine specimens, may produce erroneous test results regardless of the analysis method used. If adulteration is suspected, obtain another urine specimen.
5. There is the possibility that other substances and/or factors not listed may interfere with the test and cause false results, e.g. technical or procedural errors.
6. A positive result indicates the presence of benzoylecgonine in urine. This result does not indicate the level of intoxication nor is it intended to monitor drug levels.
7. Results should be confirmed using an alternate method. GC/MS is the preferred confirmatory method.

REFERENCES

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3. CSAP Technical Report 12 Urine Specimen Collection Handbook for Federal Workplace Drug Testing Programs, SAMSHA, Center for Substance Abuse Prevention.
4. Pearman K: Cocaine: A review, J Laryngol Otol 1979; 93; 1191-1199.
5. Stewart DJ et al: Cocaine metabolism: Cocaine and norcocaine hydrolysis by liver and serum esterases. Clin Pharmacol Ther 1978 25: 464-468.
6. Baselt RC, Cravey RH: Disposition of Toxic Drugs and Chemicals in Man, 3rd ed., Chicago, IL, Year Book Medical Publishers Inc, 1989, pp 208-213.
7. Van Dyke C et al: Urinary excretion of immunologically reactive metabolites after intranasal administration of cocaine as followed by enzyme immunoassay. Clin. Chem 1977; 23 241-244.
8. Baselt, Randall C. Urine Drug Screening by Immunoassay: Interpretation of Results, in Baselt, Randall (ed): Advances in Analytical Toxicology, Volume 1, Biomedical Publications, Foster City. California, 1984, pp 81-123.

SYMBOLS USED IN PRODUCT LABELING



- contents



- catalogue number



- consult instructions for use



- in vitro diagnostic medical device



- temperature limits



- manufacturer



- batch code / lot number



- use by / expiry date