COC Cocaine strip CE

CONTENTS			
REF	4430150	Cocaine	50 tests
For professional *in vitro* diagnostic use only			

Cocaine

A rapid test for the qualitative detection of Cocaine in human urine.
ONE STEP

PRINCIPLE

The LINEAR COC Cocaine strip is an immunoassay based on the principle of competitive binding.
Drugs that 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 300 ng/mL, will not saturate the binding sites of antibody in the test strip. 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 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 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.

REAGENT COMPOSITION

COC Cocaine test strip, contains mouse monoclonal anti-Benzoylecgonine antibody-coupled particles and Benzoylecgonine-protein conjugate. A goat antibody is employed in the control line system.

PACKAGING CONTENTS

REF 4430150 50 COC Cocaine test strip

STORAGE AND STABILITY

Store at 2-30ºC.
The test strip is stable through the expiration date printed on the sealed pouch. The test strip must remain in the sealed pouch until use. **DO NOT FREEZE.** Do not use beyond the expiration date.

SPECIMEN COLLECTION AND PREPARATION

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

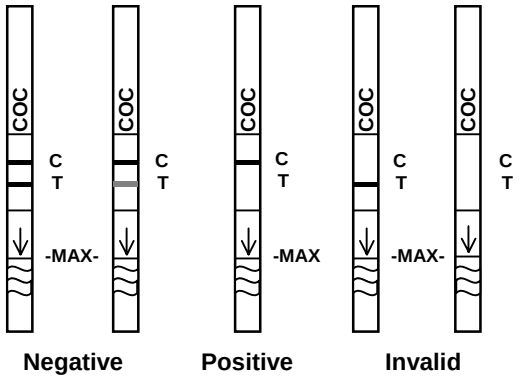
MATERIAL REQUIRED

- Timer.
- Specimen collection container .
- External controls.

PROCEDURE

Allow the test strip, 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 test strip from the sealed pouch and use it as soon as possible.
2. With arrows pointing toward the urine specimen, **immerse the test strip vertically in the urine specimen for at least 10-15 seconds**. Do not pass the maximum line (MAX) on the test strip when immersing the strip. See the illustration below.
3. Place the test strip on a non-absorbent flat surface, start the timer and wait for the red line(s) to appear. The result should be **read at 5 minutes**. Do not interpret the result after 15 minutes.



NEGATIVE:* Two lines appear. One colored line should be in the control region (C), and another apparent colored line should be in the test region (T). This negative result indicates that the Benzoylecgonine 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 region (C). No line appears in the test region (T). This positive result indicates that the Benzoylecgonine 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 strip. 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 red line appearing in the control region (C) is considered an internal procedural control. It confirms sufficient specimen volume and correct procedural technique. Control reagents are not supplied with this kit; however, it is recommended that positive and negative controls be tested as good laboratory testing practice to confirm the test procedure and to verify proper test performance.

CLINICAL SIGNIFICANCE

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 LINEAR COC Cocaine strip 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 LINEAR COC Cocaine strip 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). Test to monitor therapeutic measures related to the study and control of detoxification treatments of drug of abuse and its effects in laboratory tests.

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ANALYTICAL PERFORMANCE

A. Accuracy

The accuracy of the LINEAR COC Cocaine strip was compared and checked against a commercially available test with a threshold value of 300 ng/mL. 120 urine samples taken from volunteer test persons who claim to be non-consumers was examined under both tests. The results were 100% in agreement.

B. Reproducibility

The reproducibility of the LINEAR COC Cocaine strip was verified by blind tests performed at a four different locations. All 60 utilized samples with a COC-concentration of 150 ng/mL yielded a negative result. All 60 samples with a COC-concentration of 600 ng/ml yielded a positive result. No significant differences were observed between test results of the different evaluation sites.

C. Precision

Test precision was determined by blind tests with control solutions. Controls with a COC-concentration of 150 ng/mL yield a negative result. Controls with a COC-concentration of 450 ng/mL provide a positive result.

D. Specificity

The specificity of the LINEAR COC Cocaine strip was tested with the substances listed below, all of which can be found in a normal urine specimen. These substances were added to normal drug free urine.

The following compounds with a similar chemical structure yielded a positive result at the specified concentration:

COMPOUND	CONCENTRATION (ng/mL)
Benzoylecgonine	300
Cocain	1,000
Ecgonine	>40,000
Ecgonine Methyl Ester	>100,000

All following listed compounds reacted negative up to a concentration of 100 µg/mL.

Acetamidophene
Acetone
Albumin
Amitriptyline
Ampicillin
Aspartame
Aspirin
Atropine
Benzocaine
Bilirubin
Caffeine
Chloroquine
(+/-)-Chlorpheniramine
Chlorpheniramine
Creatine
Dexbrompheniramine
Dextromethorphan
4-Dimethylaminoantipyrine
Dopamine
Erythromycin
Ethanol
Furosemide
Glucose
Guaiacol Glyceryl Ether
Hemoglobin
Imipramine
(+/-)-Isoproterenol
Lidocaine
(+)-Naproxen
Oxalic Acid
Penicillin-G
Pheniramine
Phenothiazine
Phenylethylamine
Procaine
Quinidine
Ranitidine
Riboflavine
Sodium Chloride
Sulindac
Thioridazine
Trifluoperazine
Trimethobenzamide
Tyramine
Vitamin C

NOTES

1. The LINEAR COC Cocaine strip provides only a qualitative, preliminary analytical result. A secondary analytical method must be used to obtain a confirmed result. Gas chromatography/mass spectrometry (GC/MS) is the preferred confirmatory method.[1,2]
2. 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.
3. A positive result indicates presence of the drug or its metabolites but does not indicate level of intoxication, administration route or concentration in urine.
4. 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.
5. Test does not distinguish between drugs of abuse and certain medications.

REFERENCES

1. Baselt, R.C. Disposition of Toxic Drugs and Chemicals in Man, Biomedical Publications, 1982.
2. Urine Testing for Drugs of Abuse. National Institute on Drug Abuse (NIDA), Research Monograph 73, 1986.
3. Thomas L. eds., Labor und Diagnose, 6. ed., TH-Books Verlagsgesellschaft, Frankfurt, 2005
4. Fed. Register, Department of Health and Human Services, Mandatory Guidelines for Federal Workplace Drug Testing Programs, 53, 69, 11970, 1988.
5. McBay, A., J. Clin. Chem. 33, 33B-40B, 1987.
6. Gilman, A.G., & Goodman, L.S. The Pharmacological Basis of Therapeutics, eds. MacMillan Publishing, New York, NY, 1980.
7. Warner, Ann Interference of Common Household Chemicals in Immunoassay Methods for Drugs of Abuse, Clin. Chem. 35/4, 648-651 (1989)

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