

SERATEC[®] Drug Screen COC

REF DSC21

A visual one-step immunoassay for the qualitative detection of the cocaine metabolite benzoylecgonine in human urine. For professional *In Vitro* diagnostic use only

INTENDED USE

The SERATEC[®] Drug Screen COC is a lateral flow, one-step immunoassay for the qualitative detection of Benzoylecgonine (cocaine metabolite) in human urine at a cut-off of 300 ng/ml. This product is used to obtain a visual, qualitative result and is intended for professional use. The assay should not be used without proper supervision and is not intended for over the counter sale to lay persons.

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 National Institute of Drug Abuse (NIDA). Clinical considerations and professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are indicated.

BACKGROUND

Cocaine is derived from the leaves of the coca plant. It is a potent stimulant of the central nervous system and a local anesthetic. Among the psychological effects induced by using cocaine are euphoria, confidence and a sense of increased energy. They can be accompanied by an increased heart rate, dilation of the pupils, fever, tremors and sweating. Cocaine is excreted with the urine primarily as Benzoylecgonine in a short period of time. 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 for **24 to 60 hours** after cocaine use.

Urine based screening tests for drugs of abuse range from simple immunoassay tests to complex analytical procedures. The speed and sensitivity of immunoassays have made them the most widely accepted method for screening urine for drugs of abuse. The SERATEC[®] Drug Screen COC is based on the principle of the highly specific immunochemical reactions of antigens and antibodies which are used for the analysis of specific compounds in biological fluids. This test is a rapid, visual, competitive immunoassay that can be used for the qualitative detection of Benzoylecgonine in human urine at a cut-off concentration of 300 ng/ml.

PRINCIPLE

The SERATEC[®] Drug Screen COC is a one-step immunoassay in which a chemically labelled drug (drug conjugate) competes with the drug which may be present in urine for limited antibody binding sites. The test device contains a membrane strip which was pre-coated with drug conjugate on the test band. A colored anti-Benzoylecgonine monoclonal antibody-colloidal gold conjugate pad is placed at the right end of the membrane. In the absence of drug in the urine, the solution of the colored antibody-colloidal gold conjugate and urine moves upward, chromatographically by capillary action, across the membrane. This solution migrates to the immobilized drug conjugate zone on the test band region. The colored antibody-colloidal gold conjugate attaches to the drug conjugate to form a visible line as the antibody complexes with the drug conjugate. Therefore, the formation of a visible precipitant in the test zone occurs, when the test urine is **negative** for the drug. When the drug is present in the urine, the drug/metabolite antigen competes with the drug conjugate on the test band region for limited antibody sites on the anti-Benzoylecgonine monoclonal antibody-colloidal gold conjugate. When a sufficient concentration of drug is present, it will fill the limited antibody binding sites. This will prevent attachment of the colored antibody-colloidal gold conjugate to the drug conjugate zone on the test band region. Therefore, absence of the colored band on the test region indicates a **positive** result.

A control band with a different antigen/antibody reaction is also added to the immunochromatographic membrane strip at the control region (**C**) to indicate that the test has performed properly. This control line should always appear, regardless of the presence of drug and metabolite. This means that **negative** urine will produce **two** colored bands, and **positive** urine will produce only **one** band. The presence of this colored band in the control region also serves as 1) verification

that sufficient volume has been added, and 2) that proper flow was obtained.

STORAGE AND STABILITY

The test kit is to be stored refrigerated or at room temperature +4 – +30 °C (38-86 °F) in the sealed pouch for the duration of the shelf life.

PRECAUTIONS

- For single *in-vitro* diagnostic use.
- For professional use only
- Urine specimens may be potentially infectious. Proper handling and disposal methods should be established.
- Avoid cross-contamination of urine samples by using a new specimen collection container and specimen pipette for each urine sample.
- Do not use test device if the pouch is damaged.
- The test components of animal origin (e.g. antibodies) do not cause any danger if the test is used according to the instructions.

MATERIALS SUPPLIED IN THE KIT

- Test devices with disposable pipettes
- One instruction sheet

MATERIALS REQUIRED

- Specimen collection container
- Timer

SPECIMEN COLLECTION AND HANDLING

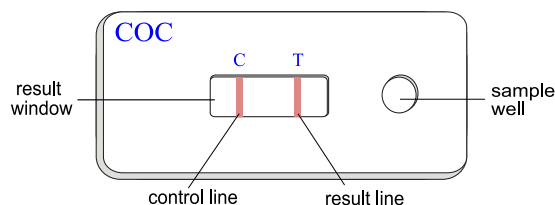
The SERATEC[®] Drug Screen COC is formulated for use with urine specimens. Fresh urine does not require any special handling or pre-treatment. Urine samples should be collected such that testing can be performed as soon as possible after the specimen collection, preferably during the same day. The specimen may be refrigerated at +2-8°C for 2 days, or frozen at -20°C for a longer period of time. Specimens that have been refrigerated must be equilibrated to room temperature prior to testing. Specimens previously frozen must be thawed, equilibrated to room temperature, and mixed thoroughly prior to testing.

Note: Urine specimens and all materials coming in contact with them should be handled and disposed of as if capable of transmitting infection. Avoid contact with skin by wearing gloves and proper laboratory attire.

TEST PROCEDURE

Review "Specimen Collection" instructions. Test device, patient's samples, and controls should be brought to room temperature (20-30°C) prior to testing. Do not open pouches until ready to perform the assay.

1. Remove the test device from its protective pouch (bring the device to room temperature before opening the pouch to avoid condensation of moisture on the membrane). Label the device with patient or control identification.
2. Draw the urine sample to the line marked on the pipette (approximately 0.2 ml). Dispense the entire contents into the sample well. Use a separate pipette and device for each sample or control.
3. Read result between **3 to 8 minutes** after the addition of sample. Do not read result after 8 minutes.



INTERPRETATION OF RESULTS

Negative result:

Two colored lines appear in the viewing window. The line in the test region (T) is the drug probe line; the line in the control region (C) is the control line, which indicates proper performance of the device. The color intensity of the test line may be weaker or stronger than that of the control line.

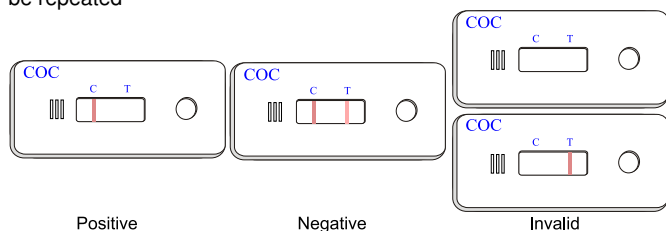
Note: A weak test line indicates that the Benzoyllecgonine concentration is close to the cut-off level. In this case the test should be repeated or the urine sample should be tested with a more specific method.

Positive result

Only one colored line appears in the control region (C). The absence of a test line indicates a positive result.

Invalid:

If no line appears in the control region the test is invalid and should be repeated



LIMITATIONS OF PROCEDURE

- The assay is designed for use with human urine only.
- A positive result with the test indicates the presence of a drug/metabolite only and does not indicate or measure intoxication.
- There is a possibility that technical or procedural errors as well as other substances and factors not listed (see SPECIFICITY) may interfere with the test and cause false results.
- If it is suspected that the samples have been mislabelled or tampered with, a new specimen should be collected.

QUALITY CONTROL

Good laboratory practice recommends the use of control materials to ensure proper kit performance. Quality control specimens are available from commercial sources. When testing the positive and negative controls, use the same assay procedure as with a urine specimen.

PERFORMANCE CHARACTERISTICS*

*to adjust the concentration of benzoyllecgonin in the non-clinical samples the Sigma Drug Standard B8900 was diluted into drug-free human urine.

A. Accuracy

The accuracy of the SERATEC® Drug Screen COC was evaluated in comparison to a commercially available immunoassay at a cut-off of 300 ng/ml. 120 urine samples, collected from presumed non-user volunteers, were tested showing negative results by both procedures with 100% agreement.

In a separate study, 69 urine samples, obtained from a clinical laboratory where they were screened and confirmed as positive by the commercially available immunoassay and GC/MS, were tested with the SERATEC® Drug Screen COC. 55 samples with Benzoyllecgonine concentrations ≥ 383 ng/ml, were found to be positive with the SERATEC® test. 10 samples with Benzoyllecgonine levels between 200-278 ng/ml showed negative test results. Of the 4 samples with Benzoyllecgonine concentrations between 340 and 360 ng/ml, 2 were determined as positive and 2 as negative, showing a very faint test line.

With the data obtained from the clinical specimens the performance characteristics of the test were calculated:

Diagnostic sensitivity:	96.6 %
Diagnostic specificity:	100 %
Positive predictive value:	100 %
Negative predictive value:	98.5 %
Reproducibility:	98.9 %

B. Reproducibility

The reproducibility of the SERATEC® Drug Screen COC test was evaluated at four different sites using blind controls. 60 of the

samples containing 150 ng/ml Benzoyllecgonine showed negative results. 60 samples with Benzoyllecgonine concentrations of 600 ng/ml were determined as positive. Of the 60 samples containing Benzoyllecgonine at the cut-off level of 300 ng/ml 91.7% were determined as (+/-), showing a very faint test line.

C. Precision

The precision of the test was determined with blind controls of the following Benzoyllecgonine concentrations: 150; 225; 375; 450 ng/ml, respectively.

Conc. (ng/mL)	samples	correct results	in %
150	94	94 (-)	100
225	94	94 (-) ¹	100
375	94	84 (+) ²	89
450	94	94 (+)	100

1: including 8 (+/-) results 2: the remaining 10 tests showed (+/-) results

D. Specificity

The specificity for the SERATEC® Drug Screen COC 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.

The following structurally related compounds produced positive results when tested at levels equal to or greater than the concentrations listed below.

Compound	Concentration (ng/mL)
Benzoyllecgonine	300*
Cocaine	300
Ecgonine	10000

* cut-off






The following compounds were found not to cross-react when tested at concentrations up to 100 µg/ml:

Acetaminophen, Albumin, Amitriptyline, Ampicillin, Aspartame, Aspirin, Atropine, Benzocaine, Bilirubin, Caffeine, Chloroquine, (+)-Chlorpheniramin, (+/-)-Chlorpheniramine, Dexbrompheniramine, Dextromethorphan, 4-Dimethylaminoantipyrine, Dopamine, Ecgonine, Ecgonine Methyl Ester, (+/-)-Ephedrine, (-)-Ephedrine, (+)-Ephedrine, (+)-Epinephrine, Erythromycin, Furosemide, Guaiacol-Glycerol-Ether, Hemoglobin, Imipramine, (+/-)-Isoproterenol-, (1R,2S)-(-)-N-Methyl-Ephedrine, Lidocaine, (+)-Naproxen, (+/-)-Norephedrine, Penicillin G, Pheniramine, Phenothiazine, L-Phenylephrine, β -Phenylethylamine, Procaine, Quinidine, Ranitidine, Sulindac, Thioridazine, Trifluorperazine, Trimethobenzamide, Tyramine, Vitamin C

SUGGESTED READING

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. Fed. Register, Department of Health and Human Services, Mandatory Guidelines for Federal Workplace Drug Testing Programs, 53, 69, 11970, 1988
4. McBay, A.J. Clin. Chem. 33, 33B-40B, 1987
5. Gilman, A.G., & Goodman, L.S. The Pharmacological Basis of Therapeutics, eds. MacMillan Publishing, New York, NY, 1980.

Symbols

	For single use only
	Expiry date
	Store at room temperature
	For in-vitro diagnostic use only
	Lot number

June 2009

