

HEALTH-CHEM DIAGNOSTICS, LLC

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ONE STEP DRUGS OF ABUSE TEST STRIP - COCAINE[®]

NAME AND INTENDED USE

The **One Step Drugs of Abuse Test Strip - Cocaine[®]** is a rapid, qualitative, competitive binding immunoassay for the determination of Cocaine and its metabolites in urine in a convenient one step strip test format. The **One Step Drugs of Abuse Test Strip - Cocaine[®]** 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) is the preferred confirmatory method.

INTENDED USE

The **One Step Drugs of Abuse Test Strip - Cocaine[®]** is a rapid, qualitative, competitive binding immunoassay for the determination of Cocaine and its metabolites in urine. The **One Step Drugs of Abuse Test Strip Cocaine[®]** is intended to be used in professional laboratories (medical & legal) where preliminary screening is essential. The test provides only preliminary data, which should be confirmed by other methods such as gas chromatography and/or mass spectrometry (GC/MS). The preliminary positive results must be substantiated with approved confirmatory methods. Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly when preliminary results are positive.

EXPLANATION OF THE TEST

The **One Step Drugs of Abuse Test Strip - Cocaine[®]** strip is an easy, fast, and visually read screening method, without the need for instrumentation.

PRINCIPLE OF THE PROCEDURE

The **One Step Drugs of Abuse Test Strip - Cocaine[®]** employs mouse monoclonal antibodies to selectively identify Cocaine and its metabolites in test samples. The **One Step Drugs of Abuse Test Strip - Cocaine[®]** is 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 a limited number of 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 and will not produce a magenta color band in the Test Zone when the drug is higher than the detection level of 300 ng/ml Cocaine HCl, or 150 ng/ml Benzoyllecgonine. Unbound dye conjugate binds to the reagent in the control zone, producing a magenta color band, demonstrating that the reagents and device are functioning correctly.

Cocaine is derived from the leaves of 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 excreted in the urine primarily as Benzoyllecgonine within a short period of time. Benzoyllecgonine has a biological half-life of 5-8 hours, which is much longer than that of Cocaine (0.5 to 1.5 hours), and can be generally detected for 24-60 hours after Cocaine use or exposure.

Immunoassay testing has been developed for the determination of Cocaine in the urine at a concentration of 300 ng/ml set by the National Institute on Drug Abuse (10).

A NEGATIVE specimen produces two distinct color bands in both the test line and control area.

A POSITIVE specimen produces only one color band in the control area.

MATERIALS REQUIRED BUT NOT PROVIDED

1. Specimen collection containers.
2. Clock or timer.
3. 13 x 100mm Test Tube.

WARNINGS AND PRECAUTIONS

1. For in vitro diagnostic use only. For professional use only (Professional medical & legal).
2. Do not use beyond the expiration date imprinted on the outside of the foil pouch, or if foil pouch is broken.
3. Urine specimens may be infectious. Upon completion of all testing, dispose of residual urine in an approved manner. Properly handle and dispose of all used reaction devices in a biohazard container.

STORAGE AND STABILITY

The reagents supplied can be stored under refrigeration (2°-8°C) (DO NOT FREEZE) or at room temperature (18°-30°C) and will be stable until the expiration date.

SAMPLE COLLECTION AND PREPARATION

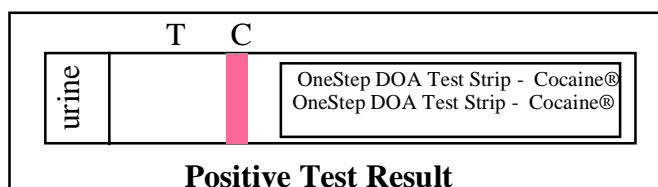
Urine (1.0 ml) - The sample must be collected in a clean, dry container, either plastic or glass, without any preservatives. Urine specimens may be refrigerated (2°-8°C) and stored up to 48 hours, or frozen (-20°C or colder) prior to assaying. If samples are refrigerated or frozen, they should be allowed to come to room temperature before testing. Urine samples exhibiting visible precipitates should be filtered, centrifuged or allowed to settle so that clear aliquots can be obtained for testing.

ASSAY PROCEDURE

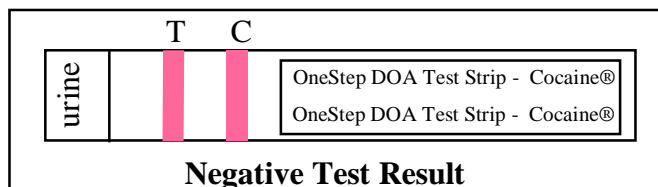
1. Remove the **One Step Drugs of Abuse Test Strip - Cocaine®** from its protective foil wrapper by tearing along the notch. **NOTE:** Refrigerated strips should be allowed to come to room temperature before opening the pouch.
2. Add 1 ml of urine to be tested to a 13 x 100mm test tube. Holding the strip in a vertical position, place it into the urine and simultaneously start timing. Make sure that only the end with the arrow pointing down is placed in the urine specimen. The urine level should not be higher than the maximum fill line indicated on the strip.
3. Read results after 3 minutes. Test results should not be interpreted after 10 minutes.

READING THE TEST RESULTS

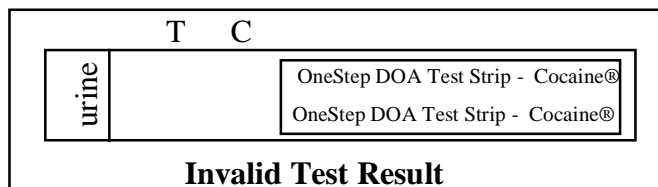
1. **POSITIVE:** One magenta band appears on the control region. No visible band on the test region (lower portion of the read area). This is an indication that the Cocaine level is above the detection sensitivity level of 300 ng/ml or the Benzoylcegonine level of 150 ng/ml.



2. **NEGATIVE:** In addition to the control band, a magenta band also appears on the test region (lower portion of the read area). If this is the case, the Cocaine level is below the detection sensitivity level of 300 ng/ml and/or the Benzoylcegonine level of 150 ng/ml.



3. **INVALID:** If there are no distinct color bands in both the upper and lower portions of the read area, or no band in the control region (upper portion of the strip), then the test results are invalid. It is recommended that the specimen be retested.



QUALITY CONTROL

1. Each reaction strip has its own built in quality control indicator. If after performing the test no line is visible on the strip, the strip may have been placed into the tube incorrectly or the test device may have deteriorated. The assay will have to be repeated using a new **One Step Drugs of Abuse Test Strip - Cocaine®**.

2. Good laboratory practice recommends the use of control material to test each product lot or whenever it is necessary to validate reagent performance and reliability. Commercial controls positive for cocaine are available for that purpose from BioRad, Utak, and Alltech. These controls should contain drugs of abuse at levels at least 20% above the NIDA recommended guidelines for drugs of abuse testing.

AFTER TESTING

Urine specimens may be infectious. Upon completion of all testing discard the residual urine in an approved manner. Properly handle and dispose of all used reaction devices in a biohazard container.

PERFORMANCE CHARACTERISTICS

Table 1 - Results of In-House Testing

SIA™	One Step (+)	One Step (-)	Row Totals
(+)	130	1	131
(-)	0	132	132
Col. Totals	130	133	263

ACCURACY

Based upon the data in Table I, the accuracy of the test is calculated to be 262/263 or 0.9962 or 99.62%.

SENSITIVITY

The **One Step Drugs of Abuse Test Strip - Cocaine®** has been designed for the detection of total Cocaine and its metabolites in urine at the detection sensitivity of 300 ng/ml for Cocaine HCl and 150 ng/ml for Benzoylcegonine, which are suggested for the immunoassay method in the NIDA Guidelines. Based upon the in house data in Table I, the calculated sensitivity is 130/131 or 0.9924.

SPECIFICITY

The **One Step Drugs of Abuse Test Strip - Cocaine®** can specifically detect Cocaine and its metabolite, Benzoylcegonine, in urine. Using the data in Table I from in house testing, the specificity is 132/132 or 1.00. **NOTE:** The **One Step Drugs of Abuse Test Strip - Cocaine®** has been designed to identify all negatives and to exclude negative samples, but where there is a potential question to err on the side of positivity., A positive test merely refers the sample for confirmatory testing.

There is no interference by the following substances at a 10 mg/ml concentration in urine:

Acetaminophen	Guaiacol
Acetylsalicylic Acid	Glycerol Ether
Aminopyrine	Hydrochlorothiazide
Amitriptyline	Imipramine
Amobarbital	Lidocaine
Amphetamine sulfate	Meperidine
Ampicillin	Methadone
Apomorphine	Methaqualone
Ascorbic Acid	Methamphetamine
Atropine	Methyprylon
Benzocaine	Morphine Sulfate
Butabarbital	Naproxen
Caffeine	Norethindrone
Calcium Hypochlorite	Penidillin
Chloroquine	Pendimetraxine
Chlorpheniramine	Pentobarbital
Chlorpromazine	Phenobarbital
Codeine	Phencylidine
Dextromethorphan	Phenolbutazone
Deoxyephedrine	Phenylpropanolamine
Diazepam	Procaine HCl
Diphenylhydantoin	Secobarbital
Epinephrine	Tetracycline

Erythromycin	Tetrahydrocannabinolcarboxylic Acid
Estriol	Tetrahydrozoline
Gentisic Acid	Trifluoperazine
Glutethimide	Zomepirac

There is the possibility that other substances and/or factors not listed above may interfere with the test and cause false results, e.g. technical or procedural errors.

LIMITATIONS OF THE TEST

1. This product is designed to be used for the detection of Cocaine and its metabolites in human urine only.
2. Although the **One Step Drugs of Abuse Test Strip - Cocaine®** is very accurate in detecting the urine Cocaine level, there is a possibility of false results due to the presence of interfering substances in the urine.
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.

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