



## ADVANCED QUALITY™ ONE STEP Cocaine(COC) TEST

(Urine)

FOR *IN VITRO* DIAGNOSTIC USE ONLY

### INTENDED USE

THE ADVANCED QUALITY™ ONE STEP COCAINE 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 300NG/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 AND EXPLANATION OF THE TEST

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 Benzoyllecgonine. Benzoyllecgonine 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.<sup>5,8</sup>

The Advanced Quality Cocaine Test detects benzoyllecgonine in urine at concentrations of 300 ng/mL and greater as recommended by SAMSHA(NIDA)<sup>2</sup>.

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.

### PRINCIPLE OF THE PROCEDURE

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.

### REAGENTS AND MATERIALS SUPPLIED

#### FOR STRIP TEST

1. Test strips individually foil pouched with a desiccant
2. Package insert

#### FOR CARD TEST

1. Test cards individually foil pouched with a desiccant
2. Plastic dropper
3. Package insert

### MATERIALS REQUIRED BUT NOT PROVIDED

1. Urine collection containers (for card test)
2. Clock or Timer
3. Positive and negative urine controls available from commercial distributors.

### WARNINGS AND PRECAUTIONS

1. For *in vitro* diagnostic use only.
2. Avoid cross contamination of urine samples by using a new urine specimen cup for each sample.
3. Do not use the kit beyond the expiration date printed on the outside of the foil pouch.
4. Do not open the foil pouch until urine specimen is collected and ready to be tested.
5. Urine specimens may be infectious. Handle and dispose of all used specimens and devices in an approved biohazard container.

### STORAGE AND STABILITY

The test device can be stored under refrigeration and at room temperature (2 - 30° C) and will be stable until the expiration date. **Do not** open foil pouch until ready to test.

### SAMPLE COLLECTION AND PREPARATION

10 ml of urine must be collected in 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.

### ASSAY PROCEDURES

#### 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 result between 3 - 8 minutes after adding the sample.

#### FOR CARD 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 result between 3 - 8 minutes after adding the sample.

### READING THE TEST 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.*

### QUALITY CONTROL

- 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.
- 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.

#### EXPECTED RESULTS

The Advanced Quality Cocaine Test identifies benzoylecgonine in human urine at a cut off concentration of 300ng/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.

#### PERFORMANCE CHARACTERISTICS

##### Accuracy

A comparative evaluation of 100 clinical urine specimens was performed using the Advanced Quality One Step Cocaine Metabolite Test and a commercially available EIA screen/semi quantitative test. Both tests have a cut off concentration of 300ng/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 Advanced Quality Cocaine Test was 88%. All results were confirmed with GC/MS benzoylecgonine testing. The twelve discrepant results were between 272-471ng/ml of benzoylecgonine.

**TABLE 1 – COMPARISON SUMMARY**

Commercial EIA	AQ(+)	AQ(-)	Row Totals
(+)	48	12	60
(-)	0	40	40
Col. Totals	48	52	100

##### Precision

Three lots of Advanced Quality Cocaine Test were assayed using urine controls containing 0ng/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 in Table 2. Some users, may find variable results up to +/- 35% of the Advanced Quality Cocaine cut off. GC/MS testing must be performed to confirm results.

**TABLE 2**

COMPOUND	LEVEL OF REACTIVITY			
Benzoylecgonine	0ng/mL	150ng/mL	300ng/mL	375ng/mL
#Tested/#Results	25/25Neg	25/25Neg	25/25Pos	25/25Pos

##### Specificity and Interfering substances

**TABLE 3 - 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 with the AQ Cocaine Test.

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

**TABLE 4 - 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	Ephedrine	Gentisic Acid	Guaiacal glyceryl ether	Histamine	Homatropine	Imipramine	Isoproterenol	Ketamine	Lidocaine	Meperidine(200ug/mL)	Methodone d,l,Me	thamphetamine d,	Methamphetamine	Morphine	Naloxone	Neomycin,	Niacinamide	11-Nor- 8-THC-9-COOH(10 ug/mL)	11-Nor-9 THC-9-COOH(10 ug/mL)	Oxazepam	Perphenazine	Phencyclidine	Phenobarbital	Phenylethylamine	5.5-diphenylhydantoin	Phenylpropanolamine	Procaine	Promethazine	Pseudoephedrine	Rantidine	Salicylic Acid	Secobarbital	Tetracycline	Tetrahydrozoline	Theophylline	Thioridazine	Trifluoperazine
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#### LIMITATIONS OF THE TEST

- This product is designed to be used for the detection of benzoylecgonine in human urine only.
- Although the Advanced Quality One Step Cocaine Metabolite Test is very accurate in detecting Cocaine metabolites in urine, there is a possibility of false results due to the presence of interfering substances.
- The test is a qualitative screening assay and is not suggested for determining the quantitative Cocaine level of urine.
- 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.
- 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.
- 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.
- Results should be confirmed using an alternate method. GC/MS is the preferred confirmatory method.

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