

# Cocaine Card Test

## INTENDED USE

The One Step Cocaine/Benzoyl Ecgonine assay is a rapid, qualitative, competitive binding immunoassay for the determination of benzoyl ecgonine in human urine. The test provides only preliminary data which should be confirmed by other methods<sup>1, 2,3,4</sup> such as gas chromatography / mass spectrophotometry (GC/MS). The preliminary positive results should be justified with compelling clinical consideration and professional judgment.

## SUMMARY AND EXPLANATION OF THE TEST

The method employs unique monoclonal antibodies to selectively identify benzoyl ecgonine in test samples with a high degree of sensitivity. Cocaine is an alkaloid present in the Coca leaves (*Erythroxylon coca*) and its pharmacological properties, such as stimulating and euphoric effects, have been known for many centuries.<sup>5</sup> Cocaine has been used medicinally as a local anesthetic agent, but its addictive properties have minimized its modern daily use.<sup>6</sup> Cocaine is most often self-administered by IV injection, nasal insufflation, (snorting) and by inhaling vapor from heating of free base (smoking). The availability of "crack" (a street form of free base) has increased the use by this latter route.<sup>7</sup> Elimination of cocaine is predominantly controlled by its biotransformation. Very low concentrations of cocaine are detected in urine during the initial several hours, and benzoyl ecgonine, a hydrolytic degradation product, persists in urine at a detectable level for 48 hours.<sup>8</sup> Immunoassay testing has been developed for the determination of benzoyl ecgonine in the urine at the concentration of 300 ng/ml set by the National Institute on Drug Abuse.<sup>9</sup> The OneStep Cocaine/Benzoyl Ecgonine test kit is an easy, fast, and visually read screening method without the need for instrumentation.

## PRINCIPLE OF THE TEST

The One-Step Cocaine/Benzoyl Ecgonine Test 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 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 pink-rose color band when the drug is higher than the detection level of 300 ng/ml. Unbound dye conjugate binds to the reagent in the negative control zone, producing a pink-rose color band, demonstrating that the reagents and device are functioning correctly. A negative specimen produces two distinct color bands in both the test line and reference line. A positive specimen produces only one color band in the reference line.

## REAGENTS AND MATERIALS SUPPLIED

Each kit contains 20 protected foil pouches. Each pouch contains one "reaction device" and one disposable plastic dropper. The reaction device contains a drug-protein conjugate

coated membrane and a pad containing the antibody-dye conjugate in a protein matrix containing a 0.1 % sodium azide.

## MATERIALS REQUIRED, BUT NOT PROVIDED

1. Specimen collection containers
2. Clock or Timer

## WARNINGS AND PRECAUTIONS

1. For *in vitro* diagnostic use only.
2. For professional use only.
3. Do not use kit beyond expiration date imprinted on the outside of the kit box.
4. Urine specimens may be infectious. Properly handle and dispose of all used reaction devices in a biohazard container.

## STORAGE

The reagents contained in the OneStep Cocaine/Benzoyl Ecgonine test kit should be stored at room temperature (15-30°C) and will be stable until the expiration date.

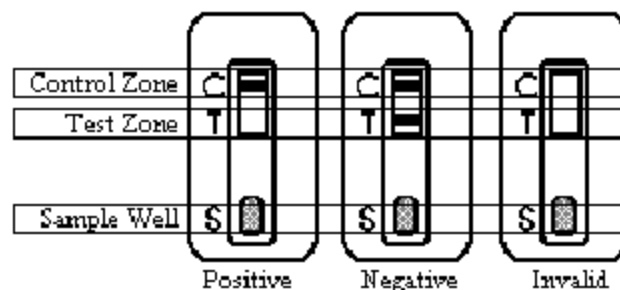
## SAMPLE COLLECTION AND PREPARATION

Urine (1.0ml) - 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, they must be equilibrated to room temperature before testing.

## ASSAY PROCEDURE

1. Bring the test kits to room temperature before opening the pouch.
2. Remove the reaction device from its foil wrapper by tearing along the "splice" and place it on a flat surface.
3. Fill the urine dropper with sample by holding the dropper vertically and dispense two to three (2 - 3) full drops of urine (without air bubbles) into the sample well.
4. Read results at 5 minutes.

## INTERPRETATION OF RESULTS



**Positive:** One pink-rose band appears on the control region. No apparent band in the test region (T), in which the benzoyl ecgonine level is above the detection sensitivity level of 300 ng/ml.

**Negative:** In addition to the control band, a pink-rose band

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also appears in the test region (T). If this is the case, the benzoyl ecgonine level is below the detection sensitivity level of 300 ng/ml.

**Invalid:** If there is no distinct color band visible both in the “T” and “C” region, or there is a visible band only in the “T” region and not the “C” region, then the test is invalid. It is recommended that the specimen be retested.

**NOTE:** In order to prevent any incorrect results, the test results should not be interpreted after 5 minutes.

## QUALITY CONTROL

1. An internal procedure control has been incorporate into the test to ensure product performance and reliability.
  2. Good laboratory practice dictates the use of control material to test each product shipment, or whenever necessary, to validate reagent performance and reliability
- Commercial controls are available for the purpose.

## LIMITATIONS

1. This product is designed to be used for the detection of Cocaine and its metabolites in human urine only.
2. Although the OneStep Cocaine/Benzoyl Ecgonine test is very accurate in detecting the urine benzoyl ecgonine level, there is a possibility of false results due to the presence of interfering substance in the urine.
3. The test is a qualitative screening assay and is not suggested for determining the quantitative benzoyl ecgonine level of urine, or the level of intoxication.
4. Adulterants, such as bleach or other strong oxidizing agents, when added to urine specimens, may produce erroneous test results regardless of the analyst method used. If adulteration is suspected, obtain another urine specimen.

## PERFORMANCE CHARACTERISTICS

### Sensitivity

The OneStep Cocaine/Benzoyl Ecgonine test had been designed for the detection of benzoyl ecgonine in urine at the detection sensitivity of 300 ng/ml, which is suggested for the immunoassay method.

### Specificity

The OneStep Cocaine/Benzoyl Ecgonine test can specifically detect benzoyl ecgonine in urine. There is no interference by the following substances at a 10 ug/ml concentration in urine: Morphine Cannabidiol (+), Amphetamine (+), Deoxyephedrine, Phencyclidine, and Phenobarbital.

## REFERENCES

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