



# CORTEZ DIAGNOSTICS, INC.

23961 Craftsman Road, Suite E/F,  
Calabasas, CA 91302 USA

Tel: (818) 591-3030 Fax: (818) 591-8383

E-mail: onestep@rapidtest.com

Web site: www.rapidtest.com

		See external label		2°C-30°C
	Σ=25 or 50 tests		Cat. #121040-1	

## Cocaine Rapicard™ Test

### OneStep Urine Cocaine (BEG) Test

Cat. No. 121040-1

#### INTENDED USE

The Cortez Diagnostic's Rapicard *OneStep* Cocaine Test is a rapid, qualitative, competitive binding immunoassay for the determination of cocaine and its metabolites in urine at or above the cutoff level of 300 ng/ml. Cortez Diagnostics's Rapicard OneStep Cocaine Test is not intended to monitor drug levels, but only to screen urines for the presence of cocaine and its metabolites.

*Note: The test provides only preliminary data that should be confirmed by other methods such as gas chromatography/mass spectrometry (GC/MS). 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

The Cortez Diagnostics Rapicard OneStep Cocaine Test is an easy, fast, and visually read competitive binding immunoassay method for screening without the need for instrumentation to arrive at a determination. The method employs a unique monoclonal antibody to selectively identify Cocaine in test samples with a high degree of sensitivity .

Cocaine is an alkaloid present in Coca leaves (Erythroxine coca). Its pharmacological properties, such as stimulating and euphoric effects, have been known for 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 (intravenous) injection, nasal insufflation (snorting), and inhalation of vapor from the heating of the free base (smoking). The availability of "crack" (a street form of the 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 urine at concentrations of 300 ng/ml or greater, the sensitivity set by the National Institute on Drug Abuse.<sup>9</sup>

#### PRINCIPLE OF THE TEST

The Rapicard *OneStep* Cocaine 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 for limited antibody sites. As the test sample flows up through the absorbent device, the free drug in the specimen competes with immobilized antigen conjugate in the test zone by binding to the antibody-dye conjugate forming an antibody-antigen complex and preventing the formation of a rose-pink color band when the drug is above the detection level of 300 ng/ml.

In the case where free drug in the sample is below the detection level of 300 ng/ml, antibody-dye conjugate is free to bind to the immobilized antigen in the test zone, producing a rose-pink color band. Furthermore, unbound dye conjugate binds to the reagent in the control zone, producing a rose-pink color band, demonstrating that the reagents and device are functioning correctly.

Cortez Diagnostics, Inc. 23961 • Craftsman Rd., Suite D • Calabasas, California 91302 USA

Tel: (818) 591-3194 • Fax: (818) 591-0393 • E-mail: onestep@rapidtest.com • Website: http://www.rapidtest.com

A **NEGATIVE** specimen produces two distinct color bands in the test zone and control zone. A **POSITIVE** specimen produces only one color band in the control zone..

#### REAGENTS AND MATERIALS PROVIDED

1. Test Cassette The test device contains membrane-immobilized reagents in a protein matrix containing sodium azide. *Cat. # 12000*

- |                          |   |
|--------------------------|---|
| 2. Droppers              | Sealed in foil pouch with test device.<br><i>Cat. # PIP-003</i> |
| 3. Urine Cups (optional) | <i>Cat. # UCP-001</i>   |
| 4. Test Instructions     | <i>Cat. # PI-12000</i>  |

#### MATERIALS REQUIRED BUT NOT PROVIDED

1. Watch or timer.
2. Sample collection containers.

#### WARNINGS AND PRECAUTIONS

1. For *in vitro* diagnostic and professional use only.
2. Do not use the test cassette beyond the expiration date.
3. Urine specimens may be infectious; properly handle and dispose of all used reaction devices in the biohazard container.
4. Visually inspect the foil package to insure it is intact. If the package is not intact, discard the device.

#### STORAGE AND STABILITY

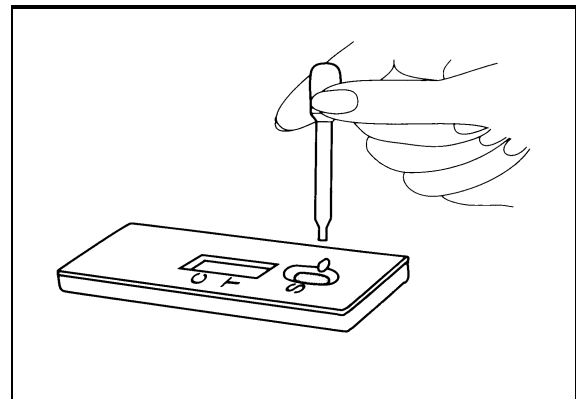
Store test kit below 28 °C; do not freeze. Refer to the expiration date for stability.

#### SAMPLE COLLECTION AND PREPARATION

The sample must be collected in clean, dry container, either plastic or glass, without any preservatives. Urine specimens may be refrigerated (2 -8 °C) and stored up to forty-eight hours, or frozen (-20 °C or below) 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.

#### TEST PROCEDURE

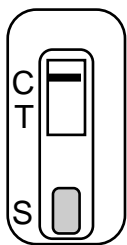
1. Bring the test components and urine sample to room temperature (15-28°C). Do not open the foil pouch until ready to begin testing.
2. Open the foil pouch at the notch and remove the test device. Place the device on a clean, flat surface.
3. Holding the dropper vertically as shown, add 4 drops (~ 120 μl) of urine to the sample well "S."



4. Read the result at 5 minutes.

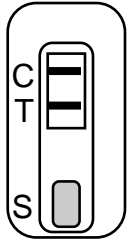
**IMPORTANT:** Do not interpret a test result after more than five minutes. Waiting longer than five minutes may cause inaccurate interpretation. To avoid confusion, discard the test device after reading the result at five minutes.

**INTERPRETATION OF RESULTS**



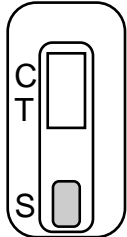
**POSITIVE**

The control line appears in the test window, but the test line is not visible. Cocaine concentration in the test sample is 300 ng/ml or more.



**NEGATIVE**

Two pink-rose lines (bands) are visible in the control ("C") and test ("T") areas of the test window. Cocaine level in the urine sample is below the InstaTest Cocaine sensitivity of 300 ng/ml.



**INVALID**

The test is invalid if the control line is not visible at five minutes. The test failed, or the test procedure was not followed properly. Verify the test procedure and repeat the test with a new testing device.

- Positive.** One *rose-pink* color band appears in the Control Zone ("C"), but not in the Test Zone ("T"). A positive result indicates that benzoyl ecgonine levels are at or above 300 ng/ml.
- Negative.** Two *rose-pink* color bands appear-- one in the Control Zone ("C") and one in the Test Zone ("T"). A negative result indicates that benzoyl ecgonine levels are below 300 ng/ml.
- Invalid.** No *rose-pink* color bands appear, or a band appears in the Test Zone ("T"), but not in the Control Zone ("C"). An invalid result may be due to improper testing procedures or deterioration of the kit components. Repeat the assay sequence using a new device.

*Note: There is no meaning attributed to line color intensity or width.*

**QUALITY CONTROL**

An internal procedure control has been incorporated into the test to ensure proper kit performance and reliability.

The use of an external control is recommended to verify proper kit performance. Quality control samples should be tested according to quality control requirements established by the testing laboratory.

**LIMITATIONS OF THE TEST**

- This product is designed for use with human urine only.
- Although the test is very accurate in detecting cocaine in urine, there is a possibility false results will occur due to the presence of interfering substances in the urine and/or factors beyond the control of the manufacturer, e.g. technical or procedural errors associated with the testing.
- The test is a qualitative screening assay and is not for determining quantitative concentration levels or the level of intoxication.
- 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 and retest.

**PERFORMANCE CHARACTERISTICS**

- Sensitivity.** The RapiCard *OneStep* Cocaine Test detects cocaine and the major metabolites of cocaine in urine at concentrations equal to or greater than 300 ng/ml, which is suggested by NIDA for the immunoassay method.
- Specificity.** A study was conducted with the RapiCard *OneStep* Cocaine Test to determine the cross-

reactivity of non-cocaine related compounds with the test at concentrations much higher than normally found in the urine of people using or abusing them. No cross-reactivity was detected with the substances listed in **Table I**.

A separate study was conducted to determine the cross-reactivity of cocaine-related compounds with the test. Substances listed in **Table II** produced results approximately equivalent to the cut-off level for cocaine.

**Table-I: Compounds tested and found not to cross-react with the test at a 10mg/ml concentration in urine:**

- Acetaminophen*
- Acetylsalicylic Acid*
- Amikacin*
- Amitriptyline*
- Ampicillin*
- Arterenol*
- Aspartame*
- Atropine Sulfate*
- Benzoic Acid*
- Benzoyllecgonine HCl*
- Caffeine*
- Chlorpheniramine*
- Chlorpromazine HCl*
- Cimetidine*
- Codeine*
- Deoxyephedrine*
- Dextromethorphan*
- Diazepam*
- Diethylpropion*
- Dephenylhydantoin*
- Doxylamine*
- Ecgonine HCl*
- Ecgonine Methyl Ester*
- Glucose*
- Histamine*
- Hydrocodone*
- Hydromorphone*
- Indomethacin*
- Ketoprofen*
- Levorphanol*
- $\Delta$ -9-THC

**Table-II: Concentration of cocaine-related compounds showing a positive response approximately equivalent to the cocaine cutoff set for the test.**

Compound / Concentration in ng/ml	
<i>Cocaine</i>	300
<i>Benzoyl Ecgonine</i>	300
<i>Isosuxprine</i>	1500

- Accuracy.** An independent correlation study was performed using positive and negative urine specimens. Each urine specimen was tested with the RapiCard *OneStep* Cocaine Test and a commercially available test (Syva<sup>®</sup>EMIT II). Positive results were confirmed by GC/MS. The results are summarized as follows:

	<u>Syva EMIT II Positive</u>	<u>Syva EMIT II Negative</u>
<b>RapiCard Positive</b>	41	0
<b>RapiCard Negative</b>	1	61

When compared to Emit II the relative sensitivity was 98.38%. The relative specificity was 100%. The concordance of the combined date with respect to Emit II was 99.03%.

4. **Precision.** The precision was determined by replicate assays of three different patient urine samples with kits from three different production lots. The resultant data indicated 100% precision for the duplicates within each lot and no appreciable interlot variation when testing both positive and negative spiked samples across three (3) different lots of devices.

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