Diagnostic Automation / Cortez Diagnostics, Inc.
IMMUNO DIAGNOSTICS

CE

OneStep Cocaine Urine RapiDip™ InstaTest

REF 121041-1-19

IVD See external Label 15-30°C ∑=50 Tests

Sensitivity	300 ng/ml

One step assay, show rapid visual results. For qualiatuve in vitro diagnostic use.

INTENDED USE

The Cortez Diagnostics, Inc. OneStep Cocaine Urine RapiDip™ InstaTest is a qualitative immunoassay, which is intended to be used to assess the usage of cocaine by detecting benzoylecgonine, a metabolite of cocaine, in human urine at a cutoff level of 300 ng/ml. It is for health care professional use only.

This assay provides only a preliminary result. A more specific alternate chemical method must be used in order to obtain a confirmed analytical result. Gas Chromatography / Mass Spectrometry (GC/MS) is the preferred confirmatory method. Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are obtained.

SUMMARY AND EXPLANATION

Cocaine (benzoylegonine) is one of the nervous systems stimulating drug with pharmacological properties, such as local anesthetic. It has addictive effects leading to substance abuse. Cocaine may appear in urine for only few hours after use, whereas the benzoylecgonine, a hydrolytic degradation product of cocaine, may be detectable in urine over 2 days after taking cocaine. Therefore the detection of benzoylecgonine in human urine has been widely used to evaluate cocaine usage.

TEST PRINCIPLE

The Cortez Diagnostics, Inc. This assay is a one-step lateral flow chromatographic immunoassay. The test strip includes 1) a burgundy-colored conjugate pad containing mouse anti-benzoylecgonine antibodies coupled to colloidal gold; and 2) nitrocellulose membrane containing a Test (T) line and a Control (C) line. The Test line is coated with benzoylecgonine-BTG, and the Control line is coated with goat anti-rabbit IgG antibody.

This test is a competitive binding immunoassay. The benzoylecgonine in the urine specimen competes with the benzoylecgonine–BTG antigen coated on the nitrocellulose membrane for the limited binding sites of the conjugated anti-benzoylecgonine antibodies.

When an adequate amount of urine specimen is applied to the sample pad of the device, the urine specimen migrates by capillary action through the test strip. If the level of benzoylecgonine in the urine specimen is below the cutoff (300 ng/ml), the Test line should appear as a visible burgundy line. If the level of benzoylecgonine in the urine specimen is at or above the cutoff, no Test line develops.

The C line binds to the gold-conjugated rabbit IgG and forms a burgundy color line regardless of the presence of benzoylecgonine.

SPECIMEN COLLECTION

1. Each urine specimen must be collected in a clean container. Do not mix specimens.
2. Specimens may be kept at 15-30°C (59-86°F) for 8 hours, at 2-8°C for up to 3 days and at -20°C or lower for long term storage.

MATERIALS AND COMPONENTS

Materials provided with the test kits

- 50 test strips, each sealed in a pouch with a desiccant.
- 1 package insert (Instructions for Use).

Materials required but not provided

- Specimen collection containers
- Timer

PRECAUTION

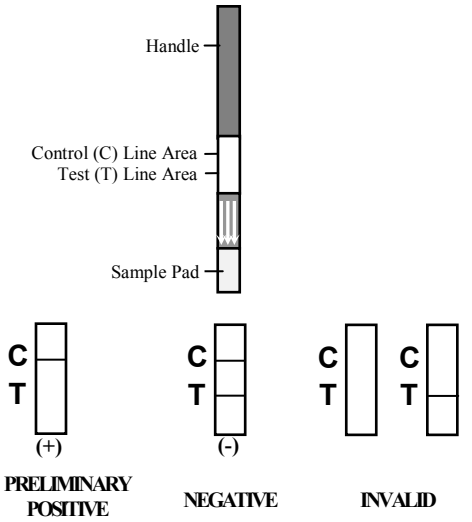
1. The instructions must be followed exactly to obtain accurate results.
2. Do not open the sealed pouch, unless ready to conduct the assay.
3. Do not use expired devices.
4. Dispose of all specimens and used assay materials as potentially biohazardous.

ASSAY PROCEDURE

1. Refrigerated specimens and other test materials, including devices, **must be equilibrated to room temperature before testing**.
2. Open the foil pouch at the notch and remove the test device.
3. Dip the device in the specimen for at least 10 seconds. Keep the specimen surface at the level indicated by the arrow sign on the device.
4. Remove the device from the specimen, and place it on a flat, dry surface.
5. Read the test result between four (4) to seven (7) minutes after adding the specimen.

RESULTS INRWEPRETATION

***IMPORTANT*: Do not read test results after seven (7) minutes. The T Line should always be interpreted independently of the C Line.**



Positive:

If only the C line appears, the test indicates that the benzoylecgonine level in the sample is at a cutoff of 300 ng/ml or higher.

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Samples with preliminary positive results should be confirmed with a more specific method before a positive conclusion is made.

Negative:
If both the C line and T line appear, the test indicates that the benzoylecgonine level is below 300 ng/ml.
Note: A very faint T line should be considered negative.

Invalid:
If no C line develops within 5 minutes, repeat the assay with a new test device

PERFORMANCE CHARACTERISTICS

1. Accuracy

A study was performed at three different Physician's Office Laboratories (POL) and a Reference Laboratory. One hundred (100) clinical samples were blind labeled and tested. Each sample was tested at each site, and compared with GC/MS results.

The results agreed 100% with the GC/MS data of specimens at levels below 75% of the cutoff (negative) and above the cutoff (positive). Nine (9) discrepancies were observed on the specimens at the level between 75% of the cutoff and the cutoff.

The overall agreement was 97.8%.

		COC Test		Total	Agreement
		Positive	Negative		
GC/MS (ng/ml)	Drug-free	0	188	188	100%
	<75% (0~225)	0	4	4	100%
	75%~Cutoff (225~300)	9	11	20	55%
	Cutoff~125% (300~375)	24	0	24	100%
	Positive (>375)	164	0	164	100%
Total		197	203	400	97.8%

2. Precision

Precision was determined at the three different POL locations by persons with diverse educational backgrounds and work experiences. Forty-pooled drug-free human urine specimens were spiked with benzoylecgonine at different levels. All specimens were blind labeled and tested. The result is as follows:

Benz Conc (ng/ml)	No of Samples	POL 1		POL 2		POL 3	
		+	–	+	–	+	–
0	8	0	8	0	8	0	8
225	8	5	3	2	6	0	8
300	8	8	0	8	0	8	0
375	8	8	0	8	0	8	0
600	8	8	0	8	0	8	0

Results indicate an average concordance of 94.2 % with the expected results.

3. Cross-Reactivity

A study was conducted using cocaine-related compounds to determine the cross-reactivity of the test.

Cocaine and its structurally related compounds showing the lowest concentration of the drug producing a positive response equivalent to the cutoff:

Description	Concentration (ng/ml)
Cocaine	*300*
Benzoylecgonine	*300*
Isoxsuprine	*1500*

4. Interfering Substances

The following components including commonly prescribed therapeutic drugs were spiked in urine pools including 0, or 300 ng/ml cocaine were tested, with this Cocaine Urine Test. No effects were observed from those analytes at concentrations of 1.0 mg/ml.

Compounds tested and found not to cross-react with the results of the test at 0 ng/ml or 300 ng/ml benzoylecgonine in human urine (Concentration at 1.0 mg/ml):

Acetaminophen	*Dextromethorphan*
Acetylsalicylic Acid	*Ethanol*
Amikacin	*Lidocaine*
Amitriptyline	*Methadone*
Ampicillin	*Methanol*
Arterenal	*Oxalic Acid*
Aspirin	*Penicillin-G (Benzylpenicillin)*
Atropine	*Phenylpropanalamine*
Benzoic Acid	*Ranitidine*
Caffeine	*Salicyclic Acid*
(+)-Chlorpheniramine	*Thioridazine*
Codeine	*Trifluoperazine*
Cortisone	

Biological Analytes	Concentration
Albumin(serum)	*2,000 µg/ml*
Bilirubin	*1,000 µg/ml*
B. Creatine	*1,000 µg/ml*
Hemoglobin	*1,000 µg/ml*
Glucose	*2,000 µg/ml*
Vitamin C (L-Ascorbic Acid)	*1,000 µg/ml*
Uric Acid	*1,000 µg/ml*
pH	*5.0-9.0*

There is a possibility that other substances and/or factors not listed may interfere with the test and cause false results

QUALITY CONTROL

- **Built-in Control Features**
  This test contains a built-in control feature, the C line. The appearance of the C line indicates that an adequate volume of specimen has been absorbed and capillary flow has occurred. The C line should always appear. If the control line does not develop within 5 minutes, review the whole procedure and repeat test with a new device.
- **External Quality Control**
  Users should always follow the appropriate federal, state, and local guidelines concerning the running of external quality controls. SAMHSA recommends that the concentration of drug(s) in positive and negative controls be approximately 25% above and below the cutoff concentration of the assay.

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LIMITATIONS

1. This test is for *professional in vitro* diagnostic use only.
2. Results obtained by this device provide only a preliminary qualitative result. A more specific alternate chemical method must be used in order to obtain a confirmed result.
3. This product is designed for testing human urine only.
4. Adulterants such as bleach or other strong oxidizing agents may produce erroneous test results if present in the sample. When suspected, collect a fresh specimen and repeat the test with a new device.
5. Samples in which bacterial contamination is suspected should not be used. These contaminates may interfere with the test and cause false results.

EXPECTED VALUES

This test is capable of detecting benzoylecgonine at a cutoff level of 300 ng/ml or higher.

STORAGE AND STABILITY

Store the kit at room temperature 15-30°C (59-86°F). Each device may be used until the expiration date printed on the label if it remains sealed in its foil pouch containing desiccant.

Do not freeze and/or expose the kit to temperatures over 30°C (86°F). **15°** **30°C**

REFERENCE

1. FDA Guidance for Labeling Urine Drugs of Abuse Screening Testing, Kshit Mohan, 7/21/87.
2. Urine Testing for Drugs of Abuse. National Institute on Drug Abuse (NIDA): Research Monograph 73, 1986.
3. Baselt, R.C. Disposition of Toxic Drugs and Chemicals in Man, 4th ED., Biomedical Publ., Davis, CA; p186-1988, 1995.
4. Department of Health and Human Services, Mandatory Guidelines for Federal Workplace Drug Testing Programs, Fed. Register, p. 53 (69): 11970 (1988).

ISO 13485 ISO 9001 **Diagnostic Automation/ Cortez Diagnostics, Inc. 21250 Califa St, Suite 102 and 116, Woodland Hills, California 91367 USA**	
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