INSTANT-VIEW® Cocaine (Benzoylecgonine) Urine Test *(Cassette)* CE

One Step Assay
Rapid Visual Results
For Qualitative In Vitro Diagnostic Use

INTENDED USE
This device is a qualitative immunoassay intended to be used to evaluate 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 OF THE TEST
Cocaine is a nervous system stimulant that can be addictive. 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 is widely used to evaluate cocaine usage.

PRINCIPLE OF THE PROCEDURE
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.

REAGENTS AND MATERIALS SUPPLIED
- 25 test devices, each sealed in a pouch with a dropper pipette.
- 1 package insert (Instructions for Use).

MATERIAL REQUIRED BUT NOT PROVIDED
- Specimen collection containers
- Timer

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.

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

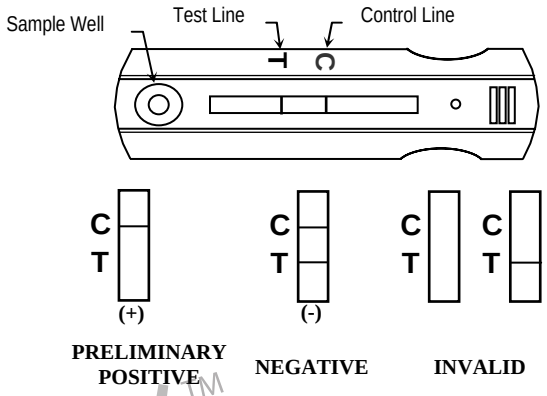
SPECIMEN COLLECTION
1. Urine specimens must be collected in a clean container. Do not mix specimens.
2. Specimens may be kept at 15-30°C (59-86°F) for 8 hours, at 2-8°C for up to 3 days and at -20°C or lower for long term storage.

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. Remove the test device from its pouch and place it on a flat surface. Label the device with specimen identification.
3. Holding the dropper vertically, add four drops of the specimen to the sample well.
4. Read the test result between four (4) to seven (7) minutes after adding the specimen.

INTERPRETATION OF RESULTS

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

Negative:
If both 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.

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. If the C line does not develop within 5 minutes, the result is invalid. In this case, 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.

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 retest with a new device.
5. Samples in which bacterial contamination is suspected should not be used. These contaminants may interfere with the test and cause false results.

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

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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 results are 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	3	5	4	4	1	7
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 93.3%.

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 analytes, commonly found in urine, were spiked in urine pools containing 0 or 300 ng/ml cocaine and tested. No effects were observed from these analytes at a concentration 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*
Creatine	*1,000 μg/ml*
Glucose	*2,000 μg/ml*
Hemoglobin	*1,000 μg/ml*
pH	*5.0-9.0*
Uric Acid	*1,000 μg/ml*
Vitamin C (L-Ascorbic Acid)	*1,000 μg/ml*

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

REFERENCES

- FDA Guidance for labeling Urine Drugs of Abuse Screening Testing, Kshit Mohan, 7/21/87.
- Urine Testing for Drugs of Abuse. National Institute on Drug Abuse (NIDA): Research Monograph 73, 1986.
- Baselt, R.C. Disposition of Toxic Drugs and Chemicals in Man, 4th ED., Biomedical Publ., Davis, CA; p186-188, 1995.
- Department of Health and Human Services, Mandatory Guidelines for Federal Workplace Drug Testing Programs, Fed. Register, p. 53 (69): 11970 (1988).

30°C 15°C	Temperature limitation		Use by YYYY-MM
LOT	Batch/Lot code	IVD	*In vitro* diagnostic medical device
	Manufacturer	REF	Catalog number
Σ n	Contains sufficient for < n > tests		Consult instructions for use
	For IVD performance evaluation only	2	Do not reuse
	Caution, consult accompanying documents	CE	CE Mark

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