Rapid Drugs (Cocaine) Screening Test Kit

(Urine)

The Rapid Drugs (Cocaine) Screening Test Kit is a rapid chromatographic immunoassay for the qualitative detection of Cocaine (COC) in human Urine specimens.

For *In-Vitro Diagnostic* Use only

ORDER INFORMATION

Pack Size	REF
01 Test	PCOC 01
05 Tests	PCOC 05
10 Tests	PCOC 10
25 Tests	PCOC 25
50 Tests	PCOC 50

CLINICAL SIGNIFICANCE

COC (Cocaine) is derived from the leaves of cocoa plant. The cocaine drug is used by smoking, intravenous, intranasal or oral administration and excreted in the urine primarily as benzoylecgonine in a sort period. Benzoylecgonine has biological half-life of 5 to 8 hours, which is much longer than that of the cocaine drug (0.5 to 1.5 hours), and can be generally detected for 12 to 72 hours after cocaine drug use or exposure. The cutoff leval for this cocaine drug test is 300 ng/ml of benzoylecgonine. The test is most often used to screen for drug use. It's often required by the court system and some workplaces.

PRINCIPLE

The Rapid Drugs (Cocaine) Screening Test Kit (Urine) detects Cocaine through visual interpretation of color development on the strip. The assay relies on the competition for binding antibody**.** Drug conjugates are immobilized on the test region of the membrane. During testing, the specimen reacts with antibodies conjugated to colored gold nano particles. The mixture then migrates through the membrane by capillary action, and interacts with reagents on the membrane. If there are insufficient drug molecules in the specimen, the antibody-colored particle conjugate will bind to the drug conjugates, forming a colored band at the test region of the membrane. Therefore, a colored band appears in the test region when the urine is negative for the drug. If drug molecules are present in the urine above the cut-off concentration of the test, they compete with the immobilized drug conjugate on the test region for limited antibody binding sites. This will prevent attachment of the antibody-colored particle conjugate to the test region. Therefore, the absence of a colored band at the test region indicates a positive result. The appearance of a colored band at the control region serves as a procedural control, indicating that the proper volume of specimen has been added and membrane wicking has occurred**.**

KIT COMPONENTS

• Test Cassettes • Droppers • Package Insert

MATERIALS REQUIRED BUT NOT PROVIDED

• Specimen Collection Containers • Timer

PRECAUTIONS

1. For professional *in vitro* diagnostic use only. Do not use after the expiration date.
2. Wear protective gloves while handling specimens wash thoroughly afterwards.
3. The device is sensitive to humidity as well as heat. Therefore, take out the device from seal pouch before test.
4. Do not mix reagents from different lot.
5. Dispose all the samples and kits properly as per the instruction after test in accordance in GLP.
6. Follow the testing procedure exactly as mention in the insert.

STORAGE AND STABILITY

1. The kit can be stored at room temperature or refrigerated (2-30°C). The test device must remain in the sealed pouch until use. DO NOT FREEZE.
2. Do not use beyond the expiration date.
3. Do not use the test kit, if the pouch is damaged or seal is broken.

SPECIMEN COLLECTION & PREPARATION

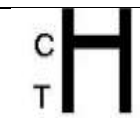
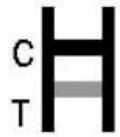
- The COC Rapid Test Strip (Urine) is intended for use with human urine specimens only.
- Urine collected at any time of the day may be used.
- Urine specimens must be collected in clean, dry containers.
- Turbid specimens should be centrifuged, filtered, or allowed to settle and only the clear supernatant should be used for testing.
- Perform testing immediately after specimen collection.
- Do not leave specimens at room temperature for prolonged periods. Urine specimens may be stored at 2-8°C for up to 2 days. For long term storage, specimens should be kept below -20°C.
- Bring specimens to room temperature prior to testing. Frozen specimens must be completely thawed and mixed well prior to testing. Avoid repeated freezing and thawing of specimens.
- If specimens are to be shipped, pack them in compliance with all applicable regulations for transportation of etiological agents**.**.

DIRECTIONS FOR USE

Allow the test device and specimen to equilibrate at room temperature (15-30°C) before testing.

1. Bring the pouch to room temperature before opening it. Remove the test cassette from the sealed pouch and use it within 1 hour.
2. Place the cassette on a clean and level surface.
3. Hold the dropper vertically and transfer 2 drops of Urine (approximately 50 µL)
4. Wait for the colored line(s) to appear. Read results at 5 minutes.
   Note: Do not interpret the result after 10 minutes.

INTERPRETATION OF RESULTS

Positive Result	
Negative Result	

1) Positive
The control line is the only visible line on the test device. This is indicative of presence of COC above 300 ng/ml
2) Negative
The control line and Test line is visible line on the test device. This no COC detected or COC below 300 ng/ml

3) Invalid
The control line fails to appear. Insufficient specimen volume or incorrect procedural techniques are the likeliest reasons for control line failure. Repeat the test using a new test device.

Quality Control

Internal procedural controls are included in the test individually. A colored line appearing in control line region (C) is the internal procedural

control. It confirms sufficient specimen volume and correct procedural technique. Control standards are not supplied with this kit; however, it is recommended that positive and negative controls be tested as a good laboratory practice to confirm the test procedure and to verify proper test performance.

Limitations of the Test

1. The COC Rapid Test Strip (Urine) is for professional in vitro diagnostic use, and should be only used for the qualitative detection of Cocaine.
2. This assay provides a preliminary analytical test result only. A more specific alternative chemical method must be used in order to obtain a confirmed analytical result. Gas chromatography/mass spectrometry (GC/MS) has been established as the preferred confirmatory method by the National Institute on Drug Abuse (NIDA). Clinical consideration and professional judgment should be applied to any test result, particularly when preliminary positive results are indicated.
3. There is a possibility that technical or procedural errors as well as other substances and factors may interfere with the test and cause false results

Performance characteristics

Cut off Value

The Rapid Drugs (Cocaine) Screening Test Kit can detect COC as low as 300 ng/ml.

Diagnostic Performance

A total of 140 normal human urine specimens were collected from human subjects and 2 positive control samples (2 different levels) tested by Rapid Drugs (Cocaine) Screening Test Kit. These specimens were confirmed by commercially available kit. Comparison for all subjects is showed in the following table.

Commercial COC Rapid Test Results	Cocaine Rapid Test		Total
	Positive	Negative	
Positive	2	0	2
Negative	3	137	140
Total	05	137	142

Relative sensitivity: 100%, Relative Specificity: 97.85%, Overall agreement: 98.59%

Precision

Between-run precision has been determined by 3 independent assays on the same 2 specimens: Three different lots of the Rapid Drugs (Cocaine) Screening Test Kit have been tested over a 3-days period using negative and positive specimens. The specimens were correctly identified >99% of the time

Specificity and cross-reactivity

The following substances were tested and confirmed did not interfere with Rapid Drugs (Cocaine) Screening Test Kit at the listed concentrations.

Substances	Concentration
Glucose	2000 mg/dl
Human Albumin	2000 mg/dl
Human hemoglobin	10 mg/dl
Urea	4000 mg/dl
Uric acid	10 mg/d

To evaluate the analog cross-reactivity of the devices, the target drug, drug metabolites and the same class compounds that may cross-react with the target drugs are tested by Cocaine screening rapid test.

All the compounds are added to drug-free urine at three different concentration levels. The final results are as following table. It displays the limits of detection for the specified drugs or their analog. Below these levels, the analog drugs show no cross-reactivity to target drugs.

Drugs derivative	Concentration (ng/ml)
Benzoylecgonine	300
Cocaine HCl	750
Cocaethylene	12,500
Ecgonine	32,000

BIBLIOGRAPHY

1. Baselt RC. Disposition of Toxic Drugs and Chemicals in Man. 2nd ed. Davis: Biomedical Publications; 1982.
2. 2. Hawks RL, Chiang CN, eds. Urine Testing for Drugs of Abuse. Rockville: Department of Health and Human Services, National Institute on Drug Abuse; 1986.
3. 3. Substance Abuse and Mental Health Services Administration. Mandatory Guidelines for Federal Workplace Drug Testing Programs. 53

GLOSSARY OF SYMBOL

	Consult Instruction for Use	LOT	Lot Number
REF	Catalog Number		Date of Manufacturing
	Store between		Use By or Expiration Date
	Manufacturer	IVD	For *in vitro* Diagnostic use only
	Keep away from sunlight	CONT	Content of the kit
	Tests per Kit		Do Not Use if Damaged
	Do not reuse		Keep Dry

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