Cocaine COC Rapid Test Strip (Urine)

INTENDED USE

The COC Rapid Test Strip (Urine) is a rapid visual immunoassay for the qualitative, presumptive detection of Cocaine in human urine specimens at the cut-off concentrations listed below:

Parameter	Calibrator	Cut-off (ng/ml)
COC (Cocaine)	Benzoylecgonine	300

PRINCIPLE

The COC Rapid Test Strip (Urine) detects Cocaine through visual interpretation of color development on the strip. Drug conjugates are immobilized on the test region of the membrane. During testing, the specimen reacts with antibodies conjugated to colored particles and precoated on the sample pad. 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.

WARNINGS AND PRECAUTIONS

- For professional in vitro diagnostic use only.
- Do not use after expiration date indicated on the package. Do not use the test if its foil pouch is damaged. Do not reuse tests.
- This kit contains products of animal origin. Certified knowledge of the origin and/or sanitary state of the animals does not totally guarantee the absence of transmissible pathogenic agents. It is therefore, recommended that these products be treated as potentially infectious, and handled observing the usual safety precautions (do not ingest or inhale).
- Avoid cross-contamination of specimens by using a new specimen collection container for each specimen obtained.
- Read the entire procedure carefully prior to performing any tests.
- Do not eat, drink or smoke in the area where the specimens and kits are handled. Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout the procedure and follow the standard procedures for proper disposal of specimens. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed.
- Humidity and temperature can adversely affect results.
- The used testing materials should be discarded in accordance with local regulations.

COMPOSITION

Materials Provided

- Individually packed test strip
- Package insert

Materials Required but Not provided

- Specimen collection container
- Timer

STORAGE AND STABILITY

- The kit should be stored at 4-30°C until the expiry date printed on the sealed pouch.
- The test must remain in the sealed pouch until use.
- **Do not freeze.**
- Care should be taken to protect the components of the kit from contamination. Do not use if there is evidence of microbial contamination or precipitation. Biological contamination of dispensing equipment, containers or reagents can lead to false results.

SPECIMEN

- 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.

TEST PROCEDURE

Bring tests, specimens to room temperature (15-30°C) before use.

1. Remove the test from its sealed pouch, and use it as soon as possible. For best results, the assay should be performed within one hour.
2. Hold the strip by the end, where the product name is printed. To avoid contamination, do not touch the strip membrane.
3. Holding the strip vertically, dip the test strip in the urine specimen for at least 10-15 seconds. Do not immerse past the maximum line (MAX) on the test strip.
4. After the test has finished running, remove the strip from the specimen and place it on a non-absorbent flat surface. Start the timer and wait for the colored band(s) to appear. The result should be read at 5 minutes. Do not interpret the result after 8 minutes.

INTERPRETATION OF RESULTS

POSITIVE: Only one colored band appears, in the control region (C). No apparent colored band appears in the test region (T).

NEGATIVE: Two colored bands appear on the membrane. One band appears in the control region (C) and another band appears in the test region (T).

INVALID: Control band fails to appear. Results from any test which has not produced a control band at the specified read time must be discarded. Please review the procedure and repeat with a new test. If the problem persists, discontinue using the kit immediately and contact your local distributor.

NOTE:

1. The intensity of color in the test region (T) may vary depending on the concentration of analytes present in the specimen. Therefore, any shade of color in the test region should be considered negative. Note that this is a qualitative test only, and cannot determine the concentration of analytes in the specimen.
2. Insufficient specimen volume, incorrect operating procedure or expired tests are the most likely reasons for control band failure.

PERFORMANCE CHARACTERISTICS

1. Precision

Precision studies were carried out for samples with concentrations of -100% cut-off, -75% cut-off, -50% cut-off, -25% cut-off, at the cut-off, +25% cut-off, +50% cut-off, +75% cut-off and +100% cut-off. These samples were prepared by spiking drug in negative samples. Each drug concentration was confirmed by GC/MS. All sample aliquots were blinded labeled and randomized. For each concentration, tests were performed two runs per day for 25 days. The results obtained are summarized in the following tables:

Result / Drug	-100% Cut-off	-75% Cut-off	-50% Cut-off	-25% Cut-off	Cut-off	+25% Cut-off	+50% Cut-off	+75% Cut-off	+100% Cut-off
Lot 1	50-/0+	50-/0+	50-/0+	48-/2+	24-/26+	47+/3-	50+/0-	50+/0-	50+/0-
Lot 2	50-/0+	50-/0+	50-/0+	48-/2+	26-/24+	47+/3-	50+/0-	50+/0-	50+/0-
Lot 3	50-/0+	50-/0+	50-/0+	47-/3+	26-/24+	48+/2-	50+/0-	50+/0-	50+/0-

2. Stability

The COC Rapid Test Strip (Urine) is stable at 4-30℃ (39-86°F) for 24 months based on the accelerated stability study at 50℃.

3. Interference

Potential interfering substances found in human urine of physiological or pathological conditions were added to drug-free urine and target drugs urine with concentration at 25% below and 25% above cut-off levels.Compounds that showed no interference at a concentration of 100μg/mL are summarized in the following tables.

Acetominophen (4-Acetamidophenol)	Ecgonine methyl ester	D,L-Octopamine
Acetophenetidin	EMDP	Oxalic acid
N-Acetylprocainamide	Erythromycin	Oxolinic acid
Acetylsalicylic acid	β-Estradiol	Oxymetazoline
Albumin	Fenoprofen	Papaverine
Aminopyrine	Furosemide	Penicillin-G
Amoxicillin	Gentisic acid	Perphenazine
Ampicillin	Hemoglobin	Phenelzine
Apomorphine	Hydralazine	Prednisone
Ascorbic acid	Hydrochlorothiazide	DL-Propranolol
Aspartame	Hydrocortisone	D-Pseudoephedrine
Atropine	O-Hydroxyhippuric acid	Quinine
Benzilic acid	3-Hydroxytyramine	Ranitidine
Benzoic acid	Ibuprofen	Salicylic acid
Bilirubin	D,L-Isoproterenol	Serotonin (5- Hydroxytyramine)
Chloralhydrate	Isoxsuprine	Sulfamethazine
Chloramphenicol	Ketamine	Sulindac
Chlorothiazide	Ketoprofen	Tetrahydrocortisone, 3-acetate
Chlorpromazine	Labetalol	Tetrahydrocortisone 3-(β-Dglucuronide)
Cholesterol	Loperamide	Tetrahydrozoline
Clonidine	Maprotiline	Thiamine
Cortisone	Meperidine	Thioridazine
(-) Cotinine	Meprobamate	Triamterene
Creatinine	Methoxyphenamine	DL-Tyrosine
Deoxycorticosterone	Nalidixic acid	Trifluoperazine
Dextromethorphan	Naloxone	Trimethoprim
Diclofenac	Naltrexone	D L-Tryptophan
Diflunisal	Naproxen	Tyramine
Digoxin	Niacinamide	Uric acid
Diphenhydramine	Nifedipine	Verapamil
Disopyramide	Norethindrone	Zomepirac
Noscapine		

4. Specificity

To test the specificity, drug metabolites and other components that are likely to interfere in urine samples were tested using three batches. The obtained lowest detectable concentration was used to calculate the cross-reactivity.

COC (Benzoylecgonine, Cut-off=300 ng/mL)	**Result** Positive at 300 ng/mL	**% Cross-Reactivity** 100%
Cocaine HCl	Positive at 750 ng/mL	40%
Cocaethylene	Positive at 12500 ng/mL	2.4%
Ecgonine	Positive at 32000 ng/mL	0.9%

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. 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.
4. Adulterants, such as bleach and/or alum, in urine specimens may produce erroneous results regardless of the analytical method used. Therefore, please preclude the possibility of urine adulteration prior to testing.
5. A positive result indicates the presence of a Cocaine only, and does not indicate or measure intoxication.
6. A negative result does not at any time rule out the presence of Cocaine in urine, as they may be present below the minimum detection level of the test.
7. This test does not distinguish between Cocaine and certain medications.

INDEX OF SYMBOLS

	Do not reuse	IVD	For in vitro diagnostic use only
4℃ 30℃	Stored between 4-30℃		Consult instruction for use
	Caution	LOT	Lot number

	Use by		Contains sufficient for <n> tests
	Keep away from sunlight		Keep dry
	Manufacturer		Do not use if package is damaged

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