

ALL TEST

COT Rapid Test Cassette (Urine)

Package Insert

REF DCT-102 English

A rapid test for the qualitative detection of Cocaine (nicotine metabolites) in human urine. For confirmation of a positive result, a confirmatory test is required.

(INTENDED USE)
The COT Rapid Test Cassette (Urine) is a rapid chromatographic immunoassay for the detection of Cocaine in human urine at a cut-off concentration of 200 ng/mL. This test will detect other related compounds, please refer to the Analytical Specificity table in this package insert.

This test provides only a preliminary and qualitative result. A more specific alternate chemical method such as GC/MS is the preferred confirmatory method. Clinical considerations and additional information are applied to any drug of abuse test result, particularly when preliminary positive results are used.

(SUMMARY)
Cocaine is the first-stage metabolite of nicotine, a toxic alkaloid that produces stimulation of the autonomic ganglia and central nervous system when in humans. Nicotine is a drug to which virtually every member of a tobacco-smoking society is exposed whether through direct contact or second-hand inhalation. In addition to tobacco, nicotine is also commercially available as the active ingredient in smoking replacement therapies such as nicotine gum, transdermal patches, and nasal sprays.

In a 24-hour urine, approximately 5% of a nicotine dose is excreted as unchanged drug with 10% as cocaine and 35% as hydroxycocaine, the concentrations of other metabolites are believed to account for less than 5%. While cocaine is largely by an inactive metabolite, its elimination profile is more stable than that of nicotine which is rapidly excreted. As a result, cocaine is considered a good biological marker for determining nicotine use. The plasma half-life of nicotine is approximately 60 minutes following inhalation or parenteral administration. Nicotine and cocaine are rapidly eliminated by the kidney; the window of detection for cocaine in urine at a cut-off level of 200 ng/mL is expected to be up to 2-3 days after nicotine use.

The COT Rapid Test Cassette (Urine) is a rapid urine screening test that can be performed without the use of an instrument. The test utilizes a monoclonal antibody to selectively detect elevated levels of Cocaine in urine. The COT Rapid Test Cassette (Urine) yields a positive result when the Cocaine in urine exceeds 200 ng/mL.

(PRINCIPLE)
The COT Rapid Test Cassette (Urine) is an immunoassay based on the principle of competitive binding. Drugs which may be present in the urine specimen compete against the drug conjugate for binding sites on the antibody.

During testing, a urine specimen migrates upward by capillary action. Cocaine, if present in the urine specimen below 200 ng/mL, will not saturate the binding sites of antibody coated particles in the test. The antibody coated particles will then be captured by immobilized Cocaine conjugate and a visible colored line will show up in the test line region. The colored line will not form in the test line region if the Cocaine level exceeds 200 ng/mL because it will saturate all the binding sites of anti-Cocaine antibodies.

A drug-positive urine specimen will not generate a colored line in the test line region because of drug competition, while a drug-negative urine specimen or a specimen containing a drug concentration less than the cut-off will generate a line in the test line region. To serve as a procedural control, a colored line will always appear at the control line region indicating that the proper volume of specimen has been applied to the test cassette.

Lot #: F-G-C-1731

The test contains mouse monoclonal anti-Cocaine antibody-coupled particles and Cocaine-protein conjugate which is employed in the control line system.

(PRECAUTIONS)

- For medical and other professional *in vitro* diagnostic use only. Do not use after the expiration date.
- The test should remain in the sealed pouch until use.
- All specimens should be considered potentially hazardous and handled in the same manner as an infectious agent.
- The used test should be discarded according to local regulations.

(STORAGE AND STABILITY)
Store as packaged in the sealed pouch either at room temperature or refrigerated (2-30°C). The test is stable through the expiration date printed on the sealed pouch. The test must remain in the sealed pouch until use. **DO NOT FREEZE.** Do not use beyond the expiration date.

(SPECIMEN COLLECTION AND PREPARATION)
Urine assay
The urine specimen must be collected in a clean and dry container. Urine collected at any time of the day may be used. Urine specimens exhibiting visible precipitates should be centrifuged, filtered, or allowed to settle to obtain a clear supernatant for testing.

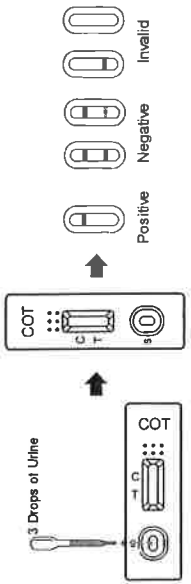
Specimen Storage
Urine specimens may be frozen and stored below -20°C. Frozen specimens should be thawed and mixed before testing.

(MATERIALS)

- Test cassettes
- Specimen collection container
- Dropers
- Package insert

(DIRECTIONS FOR USE)
Allow test urine specimen, and/or controls to reach room temperature (15-30°C) prior to testing.

- Bring the pouch to room temperature before opening it. Remove the test cassette from the sealed pouch and use it within one hour.
 - Place the test cassette on a clean and level surface. Hold the dropper vertically and transfer 3 full drops of urine (approx. 120 μ L) to the specimen well (S) of the test cassette, and then start the timer.
- Avoid trapping air bubbles in the specimen well (S). See the illustration below.



3. Wait for the colored line(s) to appear. The result should be read at 5 minutes. It is important that the background is color before the result is read. Do not interpret the result after 10 minutes.

(INTERPRETATION OF RESULTS)

NEGATIVE: Two lines appear. One colored line should be in the control line region (C), and another apparent colored line should be in the test line region (T). This negative result indicates that the Cocaine concentration is below the detectable level (200 ng/mL).

POSITIVE: One colored line appears in the control line region (C). No line appears in the test line region (T). This positive result indicates that the Cocaine concentration exceeds the detectable level (200 ng/mL).

INVALID: Control line fails to appear. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test using a new test. If the problem persists, discontinue using the lot immediately and contact your local distributor.

(QUALITY CONTROL)

A procedural control is included in the test. A colored line appearing in the control line region (C) is considered an internal positive procedural control. It confirms sufficient specimen volume, adequate specimen mixing and correct procedural technique.

Control lines appearing in the test line region (T) are considered technical failures; it is recommended that positive and negative controls be tested as good laboratory practice to confirm the test procedure and to verify proper test performance.

(LIMITATIONS)

- The COT Rapid Test Cassette (Urine) provides only a qualitative, preliminary analytical result. A secondary analytical method must be used to obtain a confirmed result. Gas chromatography/mass spectrometry (GC/MS) is the preferred confirmatory method.
- It is possible that technical or procedural errors, as well as other interfering substances in the specimen may cause a false negative result.
- Adulterants, such as bleach and/or alum, in urine specimens may produce erroneous results regardless of the analytical method used. If adulteration is suspected, the test should be repeated with another urine specimen.
- A positive result indicates presence of the drug or its metabolites but does not indicate level of intoxication, administration route or concentration in urine.
- A negative result may not necessarily indicate drug-free urine. Negative results can be obtained when drug is present but below the cut-off level of the test.
- Test does not distinguish between drugs of abuse and certain medications.

(EXPECTED VALUES)

This negative result indicates that the Cocaine concentration is below the detectable level of 200 ng/mL. Positive result means the concentration of Cocaine is above the level of 200 ng/mL. The COT Rapid Test Cassette has a sensitivity of 200 ng/mL.

(PERFORMANCE CHARACTERISTICS)

A comparison was conducted using the COT Rapid Test Cassette (Urine) and GC/MS. The following results were tabulated:

Method	Results		GC/MS		Total Results
	Positive	Negative	Positive	Negative	
COT Rapid Test Cassette	93	4	93	92	
Total Results	3	155	3	155	
% Agreement	96.7%				97.2%

Analytical Sensitivity

A drug-free urine pool was spiked with Cocaine at the following concentrations: 0 ng/mL, 100 ng/mL, 150 ng/mL, 200 ng/mL, 250 ng/mL, 300 ng/mL, and 600 ng/mL. The results demonstrate > 99% accuracy at >50% above and 50% below the cut-off concentration. The data are summarized below:

Cocaine Concentration (ng/mL)	n	Percent of Cut-off		Visual Result	
		Negative	Positive	Negative	Positive
0	30	30	0	0	0
150	30	15	15	15	3
200	30	0	30	27	3
250	30	0	30	15	15
300	30	0	30	26	26
600	30	0	30	0	30

The following table lists compounds that are positively detected in urine by the COT Rapid Test Cassette (Urine) to Cocaine

Compound	Concentration (ng/mL)
(-) Cocaine	200
(-) Nicotine	5000

Precision

A study was conducted at three hospitals by technicians using three different lots of product to demonstrate the within run, between run and between operator precision. An identical panel of coded specimens containing, according to GC/MS, no Cocaine, 25% Cocaine above and below the cut-off, and 50% Cocaine above and below the 200 ng/mL cut-off was submitted to each site. The results are given below.

Cocaine Concentration (ng/mL)	n	Site A		Site B		Site C	
		-	+	-	+	-	+
0	10	10	0	10	0	10	0
100	10	10	0	10	0	10	0
250	10	9	1	9	1	9	2
500	10	9	1	9	1	9	2
300	10	0	10	0	10	0	10

Effect of Urinary Specific Gravity

Fifteen urine specimens of normal, high, and low specific gravity ranges were spiked with 100 ng/mL and 300 ng/mL of Cocaine. The COT Rapid Test Cassette (Urine) was tested in duplicate using the fifteen neat and spiked urine specimens. The results demonstrate that varying ranges of urinary specific gravity do not affect the test results.

Effect of Urinary pH

The pH of an aliquoted negative urine pool was adjusted to a pH range of 5 to 9 in 1 pH unit increments and spiked with Cocaine to 100 ng/mL and 300 ng/mL. The spiked, pH-adjusted urine was tested with the COT Rapid Test Cassette (Urine) in duplicate. The results demonstrate that varying ranges of pH do not interfere with the performance of the test.

Cross-Reactivity

A study was conducted to determine the cross-reactivity of the test with compounds in either drug-free

urine or Cocaine positive urine. The following compounds show no cross-reactivity when tested with the COT Rapid Test Cassette (Urine) at a concentration of 100 ng/mL.

Non Cross-Reacting Compounds	Lithium carbonate
4-Acetamidophenol	Dimethylaminoacrylonitrile
Acetone	Diphenhydramine
Acetaminophen	Loperamide
Acetylsalicylic acid	Meprobamate
Albuterol	5,5-Diphenylhydantoin
Aluminum	Diazepam
Aminopyrine	Doxylamine
Amoxicillin	Egonine
Anesthetics	Egonine methyl ester
Antibiotics	EDDP
Aspirin	Ethanol (20%)
Atropine	Ethanol (50%)
Benzoin resin	Ethanol (70%)
Benzoin resin	Ethanol (90%)
Benzoin resin	Ethanol (100%)
Benzoin resin	Ethanol (110%)
Benzoin resin	Ethanol (120%)
Benzoin resin	Ethanol (130%)
Benzoin resin	Ethanol (140%)
Benzoin resin	Ethanol (150%)
Benzoin resin	Ethanol (160%)
Benzoin resin	Ethanol (170%)
Benzoin resin	Ethanol (180%)
Benzoin resin	Ethanol (190%)
Benzoin resin	Ethanol (200%)
Benzoin resin	Ethanol (210%)
Benzoin resin	Ethanol (220%)
Benzoin resin	Ethanol (230%)
Benzoin resin	Ethanol (240%)
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Benzoin resin	Ethanol (290%)
Benzoin resin	Ethanol (300%)
Benzoin resin	Ethanol (310%)
Benzoin resin	Ethanol (320%)
Benzoin resin	Ethanol (330%)
Benzoin resin	Ethanol (340%)
Benzoin resin	Ethanol (350%)
Benzoin resin	Ethanol (360%)
Benzoin resin	Ethanol (370%)
Benzoin resin	Ethanol (380%)
Benzoin resin	Ethanol (390%)
Benzoin resin	Ethanol (400%)
Benzoin resin	Ethanol (410%)
Benzoin resin	Ethanol (420%)
Benzoin resin	Ethanol (430%)
Benzoin resin	Ethanol (440%)
Benzoin resin	Ethanol (450%)
Benzoin resin	Ethanol (460%)
Benzoin resin	Ethanol (470%)
Benzoin resin	Ethanol (480%)
Benzoin resin	Ethanol (490%)
Benzoin resin	Ethanol (500%)
Benzoin resin	Ethanol (510%)
Benzoin resin	Ethanol (520%)
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Benzoin resin	Ethanol (810%)
Benzoin resin	Ethanol (820%)
Benzoin resin	Ethanol (830%)
Benzoin resin	Ethanol (840%)
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Benzoin resin	Ethanol (870%)
Benzoin resin	Ethanol (880%)
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Benzoin resin	Ethanol (960%)
Benzoin resin	Ethanol (970%)
Benzoin resin	Ethanol (980%)
Benzoin resin	Ethanol (990%)
Benzoin resin	Ethanol (1000%)

(BIBLIOGRAPHY)

- Basel RC. *Disposition of Toxic Drugs and Chemicals in Man* 6th Edition, Biomedical Publications, Foster City, CA, 2002: 744-747
- Hardman JG, Limbird LE, Goodman & Gilman's: *The Pharmacological Basis for Therapeutics*, 10th Edition, McGraw Hill Medical Publishing, 2001: 208-209.

Attention, see instructions for use	Tests per kit	Authorized Representative
IVD	Use by	Do not reuse
For in vitro diagnostic use only	Lot Number	Catalog #
Store between 2-30°C	Do not use if package is damaged	

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