



COT Rapid Test Cassette (Oral Fluid)

Package Insert

REF DCT-802	English
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A rapid test for the qualitative detection of Cotinine (nicotine metabolite) in human oral fluid. For medical and other professional in vitro diagnostic use only.

【INTENDED USE】

The COT Rapid Test Cassette (Oral fluid) is a rapid chromatographic immunoassay for the detection of cotinine in human oral fluid at the cut-off concentration of 20ng/ml. This test will detect other related compounds, please refer to Analytical Specificity table in this package insert.

This assay provides only a qualitative, preliminary, analytical test 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 used.

【SUMMARY】

Cotinine 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.

The COT Rapid Test Cassette (Oral fluid) yields a positive result when the cotinine concentration in oral fluid exceeds 20 ng/ml.

【PRINCIPLE】

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

During testing, an oral fluid specimen migrates upward by capillary action. Cotinine, if present in the oral fluid specimen below 20ng/ml, will not saturate the binding sites of the antibody coated particles in the test device. The antibody coated particles will then be captured by immobilized cotinine 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 cotinine level is at or above 20ng/ml because it will saturate all the binding sites of anti-cotinine antibodies.

A drug-positive oral fluid specimen will not generate a colored line in the test line region because of drug competition, while a drug-negative oral fluid 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 proper volume of specimen has been added and membrane wicking has occurred.

【REAGENTS】

The test contains mouse monoclonal anti-cotinine antibody-coupled particles and cotinine-nicotine conjugate. A goat antibody is employed in the control line system.

【PRECAUTIONS】

- Do not use after the expiration date.
- The test should remain in the sealed pouch until use.
- Oral fluid is not classified as biological hazard unless derived from a dental procedure.
- The used collector and cassette should be discarded according to federal, state and local regulations.

【STORAGE AND STABILITY】

Store as packaged in the sealed pouch at 2-30°C. The test is stable through the expiration date printed on the sealed pouch. The test cassettes must remain in the sealed pouch until use. **DO NOT FREEZE.** Do not use beyond the expiration date.

【SPECIMEN COLLECTION AND PREPARATION】

The oral fluid specimen should be collected using the collector provided with the kit. Follow the detailed Directions for Use below. No other collection cassettes should be used with this assay. Oral fluid collected at any time of the day may be used.

【MATERIALS】

Materials Provided

- Test cassettes
- Collectors
- Collection tubes
- Package insert

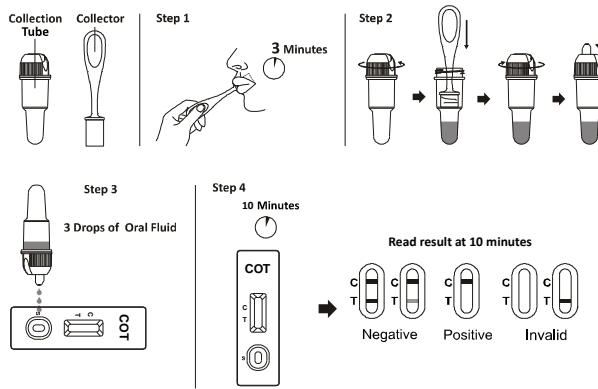
Materials Required But Not Provided

- Timer

【DIRECTIONS FOR USE】

Allow the test cassette, specimen, and/or controls to reach room temperature (15-30°C) prior to testing. Instruct the donor to not place anything in the mouth including food, drink, gum or tobacco products for at least 10 minutes prior to collection.

- Bring the pouch to room temperature before opening it. Remove the test cassette from the sealed pouch and use it within one hour.
- Remove the collector from the sealed pouch and **insert the sponge end of the collector into the mouth.** Actively swab the inside of the mouth and tongue to **collect oral fluid for a total of 3 minutes** until the sponge becomes fully saturated. Gently pressing the sponge between the tongue and teeth will assist saturation. No hard spots should be felt on the sponge when saturated.
- Remove the collector from the mouth. **Place saturated oral fluid collector into chamber and press sponge fully against the strainer to collect oral fluid.** Discard the collector. Snap the cap shut on the collection tube.
- Place the test cassette on a clean and level surface. Unscrew cap cover from the collection tube. Invert the collection tube and **transfer 3 drops of oral fluid (approximately 120 µL) into specimen well of the test cassette and start the timer.** Avoid trapping air bubbles in the specimen well. Place screw cap on the collection tube.
- Wait for the colored line(s) to appear. **Read results at 10 minutes.** Do not read results after 1 hour.



【INTERPRETATION OF RESULTS】

(Please refer to the illustration above)

NEGATIVE: Two lines appear. One color line should be in the control region (C), and another apparent color line should be in the test region (T). This negative result indicates that the Cotinine concentration is below the detectable level of 20ng/ml.

***NOTE:** The shade of color in the test region (T) may vary, but it should be considered negative whenever there is even a faint color line.

POSITIVE: One color line appears in the control region (C). No line appears in the test region (T). This positive result indicates that the Cotinine concentration is above the detectable level of 20ng/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 with a new test cassette. If the problem persists, discontinue using the test cassette immediately and contact your local distributor.

【QUALITY CONTROL】

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

【LIMITATIONS】

- The COT Rapid Test Cassette (Oral fluid) provides only a qualitative, preliminary analytical result. A secondary analytical method must be used to obtain a confirmed result. Gas chromatography/mass spectrophotometry (GC/MS) is the preferred confirmatory method.
- A positive result indicates presence of the drug or its metabolites but does not indicate level of intoxication, administration route or concentration in oral fluid.
- A negative result may not necessarily indicate drug-free oral fluid. 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.
- A positive test result might be obtained from certain foods or food supplements.

【EXPECTED VALUES】

This negative result indicates that the cotinine concentration is below the detectable level of 20ng/ml. Positive result means the concentration of cotinine is above the level of 20ng/ml. The COT Rapid Test Cassette has a sensitivity of 20ng/ml.

【PERFORMANCE CHARACTERISTICS】

Accuracy

A side-by-side comparison was conducted using the COT Rapid Test Cassette and GC/MS at the cut-off of 20ng/ml. Testing was performed on 230 clinical specimens previously collected from subjects present for Drug Screen Testing. The following results were tabulated:

Method	GC/MS		Total Results	
	Results	Positive		Negative
COT Rapid Test Cassette	Positive	131	2	133
	Negative	1	96	97
	Total Results	132	98	230
% Agreement		99.2%	98.0%	98.7%

Analytical Sensitivity

A Phosphate-buffered saline (PBS) pool was spiked with drugs to target concentrations of ±50% cut-off, ±25% cut-off and +300% cut-off and tested with the COT Rapid Test Cassette. The data are summarized below:

Cotinine Concentration (ng/mL)	Percent of Cut-off	n	Visual Result	
			Negative	Positive
0	0	30	30	0
10	-50%	30	30	0
15	-25%	30	25	5
20	Cut-off	30	20	10
25	+25%	30	7	23
30	+50%	30	0	30
60	3X	30	0	30

Analytical Specificity

The following table lists compounds that are positively detected in oral fluid by The COT Rapid Test Cassette at 10 minutes.

Compound	Concentration (ng/mL)
(-)-Cotinine	20
(-)-Nicotine	300

Cross-Reactivity

A study was conducted to determine the cross-reactivity of the test with compounds in either drug-free oral fluid or Cotinine positive oral fluid. The following compounds show no cross-reactivity when tested with The COT Rapid Test Cassette (Oral fluid) at a concentration of 100µg/mL.

Non Cross-Reacting Compounds

4-Acetamidophenol	4-Dimethylaminoantipyrine	Lithium carbonate	Phentermine
Acetone	Diphenhydramine	Loperamide	Trans-2-Phenyl cyclopropylamine
Acetofenetidin	5,5-Diphenylhydantoin	Maprotiline	(d,l-norephedrine)
Acetylsalicylic acid	Disopyramide	Mepredolone	l-Phenylephrine
N-Acetylprocainamide	Doxylamine	Mephentermine	β-Phenylethylamine
Albumin	Ecgonine	Meprobamate	Phenylpropanolamine
Aminopyrine	Ecgonine methylester	Methadone	(d,l-norephedrine)
Amitriptyline	EDDP	d-Methamphetamine	(±) Phenylpropanolamine
Amobarbital	Etavirenz (Sustiva)	l-Methamphetamine	Prednisolone
Amoxicillin	EMDP	Methqualone	Prednisone
l-Amphetamine	Ephedrine	Methoxyphenamine	5β-Pregmane-3α, 17α, 21-triol
Ampicillin	l-Ephedrine	(-) 3,4-Methylenedioxyamphetamine (MDA)	Procaine
Apomorphine	(±)-Epinephrine	(+) 3,4-Methylenedioxy-methamphetamine (MDMA)	Promazine
l-Ascorbic acid	l-Epinephrine	β-Estradiol	Promethazine
Aspartame	Erythromycin	Estrone-3-sulfate	d,l-Propranolol
Atropine	β-Estradiol	Ethanol (Ethyl alcohol)	d-Propoxyphene
Benzilic acid	Ethanol (Ethyl alcohol)	Ethyl-p-aminobenzoate	d-Pseudoephedrine
Benzoic acid	Ethyl-p-aminobenzoate	Etodolac	Methypylon
Benzoylcegonine	Etodolac	Famprofazone	Methaqualone
Benzphetamine	Famprofazone	Fenfluramine	Metoprolol
Bilirubin	Fenfluramine	Fenpropafen	Morphine-3-β-D-glucuronide
(±)-Brompheniramine	Fenpropafen	Fentanyl	Nalidixic acid
Bupropion	Fentanyl	Fluoxetine	Nalorphine
Caffeine	Fluoxetine	Furosemide	Naloxone
Cannabidiol	Gentisic acid	Chloral hydrate	Naltrexone
Cannabinol	d (+) Glucose	Chloramphenicol	Methypylon
Chloral hydrate	Guaiacol glyceryl ether	Chloridiazepoxide	Metoprolol
Chloramphenicol	Guaiacol glyceryl ether	Chloroquine	Nimesulide
Chloridiazepoxide	carbamate	Chlorothiazide	Norcodeine
Chloroquine	Hemoglobin	(+)-Chlorpheniramine	Morphine sulfate
Chlorothiazide	Hydralazine	(±)-Chlorpheniramine	α-Naphthaleneacetic acid
(+)-Chlorpheniramine	Hydrochlorothiazide	Chlorpromazine	Norethindrone
(±)-Chlorpheniramine	Hydrocodone	Chlorprothixene	Normorphine
Cholesterol	Hydrocortisone	Cholesterol	d-Norprooxyphene
Cimetidine	Hydromorphone	Clomipramine	Noscapine
Clomipramine	p-Hydroxyamphetamine	Clonidine	d,l-Octopamine
Clonidine	o-Hydroxyhippuric acid	Cocaine	Orphenadrine
Cocaine	p-Hydroxymethamphetamine	Codeine	Oxalic acid
Codeine	p-Hydroxynorephedrine	Cortisone	Oxazepam
Cortisone	Hydroxyzine	Creatinine	Oxolinic acid
Creatinine	3-Hydroxytyramine	Cyclobarbitol	Oxycodone
Cyclobarbitol	lbutoprofen	Cyclobenzaprine	Oxymetazoline
Cyclobenzaprine	Imipramine	Deoxycorticosterone	Oxymorphone
(-) Deoxyephedrine	lproniazid	(-) Isoproterenol	Papaverine
R (-) Deprenyl	Isosuprine	Dextromethorphan	Penicillin-G
Dextromethorphan	Kanamycin	Diazepam	Penicillin-G
Diazepam	Ketamine	Diclofenac	Pentabarbital
Diclofenac	Ketoprofen	Dicyclomine	Perphenazine
Dicyclomine	Labetalol	Diffunisal	Phencyclidine
Diffunisal	Levorphanol	Digoxin	Phenelzine
Digoxin	Lidocaine		Pheniramine
	Lindane		Phenobarbital
	(hexachlorocyclohexane)		Phenothiazine

Index of Symbols

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

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