

# Cotinine (COT) Rapid Test Panel(Saliva)

## INTENDED USE

The COT Rapid Test Panel (Saliva) is a rapid visual immunoassay for the qualitative, presumptive detection of cotinine in human oral fluid specimens.

Test	Cut-off (ng/mL)
Cotinine(COT)	50

## PRINCIPLE

The COT Rapid Test Panel (Saliva) is an immunoassay based on the principle of competitive binding. Drugs that may be present in the oral fluid specimen compete against their respective drug conjugate for binding sites on their specific antibody.

During testing, a portion of the oral fluid specimen migrates upward by capillary action. A drug, if present in the oral fluid specimen below its cut-off concentration, will not saturate the binding sites of its specific antibody. The antibody will then react with the drug-protein conjugate and a visible colored line will show up in the test line region of the specific drug strip. The presence of drug above the cut-off concentration in the oral fluid specimen will saturate all the binding sites of the antibody. Therefore, the colored line will not form in the test line region.

A drug-positive oral fluid specimen will not generate a colored line in the specific test line region of the strip because of drug competition, while a drug-negative oral fluid specimen will generate a line in the test line region because of the absence of drug competition. 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.

## WARNINGS AND PRECAUTIONS

- For professional *in vitro* diagnostic use only.
- Do not use after the expiration date indicated on the package. Do not use the test if the foil pouch is damaged. Do not reuse tests.
- This device contains products of animal origin. Certified knowledge of the origin and/or sanitary state of the animals does not completely guarantee the absence of transmissible pathogenic agents. It is therefore, recommended that these products be treated as potentially infectious, and handled by observing usual safety precautions (e.g., do not ingest or inhale).
- Read the entire procedure carefully prior to testing.
- Do not eat, drink or smoke in the area where specimens and devices are handled. Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout the procedure and follow standard procedures for the 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.
- Used testing materials should be discarded in accordance with local regulations.

## COMPOSITION

### Materials Provided

- Individually packed test panel
- Package insert

### Materials Required but Not provided

- Timer

## STORAGE AND STABILITY

- The test 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.
- The test should be kept out of direct sunlight.
- Care should be taken to protect the components of the test 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

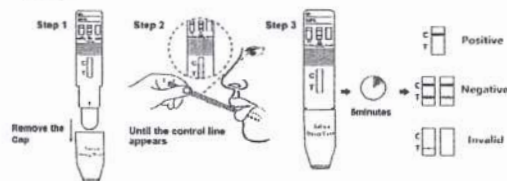
- The COT Rapid Test Panel (Saliva) is intended for use with human oral fluid specimens only.
- Oral fluid specimens must be collected according to the directions in the Test Procedure section of this package insert.
- Perform testing immediately after specimen collection.
- If specimens are to be shipped, 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. Avoid placing anything (including food, drink, gum and tobacco products) in mouth for at least 10 minutes prior to specimen collection.

- Remove the test from the sealed pouch and use it within one hour.
- Take off the cap and insert the absorbent wick to the mouth, rub the absorbent wick against the cheek and tongue gently in a circular motion about 10 times. And then place the absorbent wick underneath the tongue until the control line appears.

- Put the cap back outside of the absorbent wick and place the test on a clean and level surface. See illustration below.
- Read results at 5 minutes. If mouth is dry or saliva is sticky or little, it is suggested to extend the reading time. Do not read results after 10 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 test immediately and contact your local distributor.

### NOTE:

- 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.
- Insufficient specimen volume, incorrect operating procedure or expired tests are the most likely reasons for control band failure.

## PERFORMANCE CHARACTERISTICS

### A. Sensitivity

A phosphate-buffered saline (PBS) pool was spiked with drugs to target concentrations of 50% cut-off and 25% cut-off and tested with the COT Rapid Test Panel (Saliva). The results are summarized below.

Drug Conc. (Cut-off range)	n	COT	
		-	+
0% Cut-off	30	30	0
-50% Cut-off	30	30	0
-25% Cut-off	30	30	0
Cut-off	30	11	19
+25% Cut-off	30	1	29
+50% Cut-off	30	0	30

### B. Specificity

The following table lists the concentrations of compounds (ng/mL) above which the COT Rapid Test Panel (Saliva) identified positive results at 5 minutes.

Cotinine-Related Compounds	Concentration (ng/mL)
Cotinine	50
Buprenorphine	>100,000

A study was conducted to determine the cross-reactivity of the test with compounds spiked into drug-free PBS stock. The following compounds demonstrated no false positive results on the COT Rapid Test Panel (Saliva) when tested at concentrations up to 100 ug/mL.

Acetaminophen	Dexamethasone	(+)-Naproxen
Acetone	Diclofenac	Nifedipine
Acetophenetidine	Dicumarol	Nimesulide
Aspirin	Diffenital	Norchlorazepoxide
Albumine	Doxepin	Nordoxepinydrochloride
Atropine	D-Propoxyphene	(-)-Norketamine
Alphenal	DL-Tyrosine	Nortriptyline
α-hydroxyalprazolam	Dopamine	Olanzapine
Alprazolam	DL-Tryptophan	Opipramol
Amantadine	EDDP	Oxalic acid
Amikacin	Erythromycin	Oxymetazoline
Aminopyrine	Estroin 3 sulfate	Paroxetine
Amitriptyline	Ethanol	Pemoline
Atenolol	Etolodac	Penicillin G
Amoxicillin	(+)-Ephedrine	Perphenazine
Ampicillin	(-)-Ephedrine	Phenothiazine
Apomorphine	Flupentixol	Phenylethylamine
Aspartame	Fluoxetine	Prednisolone
Baclofen	Furosemide	Prednisone
Barbital	Gastrozepin	Protriptyline

Benzocaine	Genfamycin	Quetiapine
Bilirubin	Genisic acid	Quinidine
Butethal	Guaiacol Glyceryl Ether	Ranitidine
Carbamazepine	Glucose	Rifampicine
Cephalexin	Haloperidol	Risperidone
Chlorpheniramine	Hemoglobin	Salbutamol
Creatinine	Hexobarbital	Salicylic acid
Creatine	Hydralazine	Secobarbital
Chloramphenicol	Hydrochlorothiazide	Sertraline
Chloroquine	Hydrocortisone	Sodium chloride
Chlorpheniramine	Ibuprofen	Spiromolactone
Chlorprothixene	Insulin	Sulfamethoxazole
Cholesterol	(-)-Isoproterenol	Sulindac
Chorphenotholene	Kanamy cin	Theophylline
Cimetidine	Ketamine	Thiamine
Ciprofloxacin	L-Thyroxine	Thioridazine
Citalopram	Ketoprofen	Tobramycin
Cindamycin	L-Tyrosine	Tiazolam
Clobazam	Lincomycin	Trameterene
Clonipramine	Loperamide	Trimethoprim
Clonidine	Lidocaine	Tripropamine
Clozapine	Lindane	Valproic acid
Caffeine	Lormetazepam	Vancomycin
Cyclobenzaprine	Metoprolol	Venlafaxine
Delorazepam	Methadone	Verapamil
Desipramine	Metoprolol	Zolpidem
DL-Propranolol	Metoprolol	
Digoxin	Metronidazole	
(+)-cis-Diltiazem	Midazolam	
Dimenhydrinate	Mirtazapin	
4-Dimethylaminoantipyrine	Metoclopramide	
Diphenhydramine	N-Methyl-lepethidine	
(±)-Epinephrine	(±)-Phenylpropranolamine	
Fentanyl	β-Phenylethylamine	

## LIMITATIONS OF THE TEST

- The COT Rapid Test Panel (Saliva) is for professional *in vitro* diagnostic use, and should be only used for the qualitative detection of drugs of abuse in oral fluid.
- This assay provides a preliminary analytical test result only. A more specific analytical 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.
- 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.
- A positive result indicates the presence of a drug/metabolite only, and does not indicate or measure intoxication.
- A negative result does not at any time rule out the presence of drugs/metabolites in urine, as they may be present below the minimum detection level of the test.
- This test does not distinguish between drugs of abuse and certain medications.

## INDEX OF SYMBOLS

	Do not reuse		For in vitro diagnostic use only
	Stored between 4-30°C		Consult instruction for use
	Caution		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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