JusChek® COT Rapid Test Cassette (Oral Fluid) Package Insert

REF DCT-802 | **English**

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, 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 cassette. 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-protein 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 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
- Security seal
- Collection tubes
- Package insert

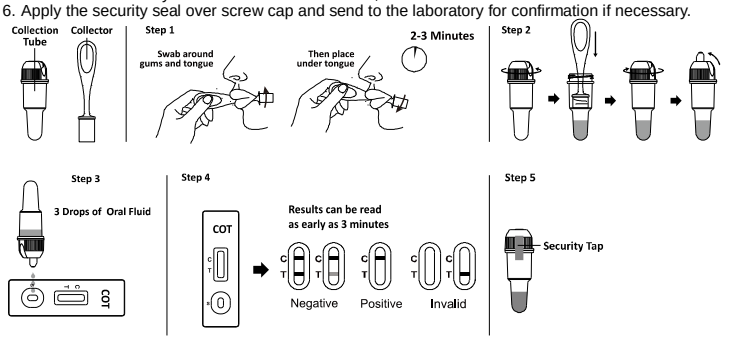
Materials Required But Not Provided

- Timer

DIRECTIONS FOR USE

Allow the test cassette, specimen, and/or controls to reach room temperature (15-30ºC) 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.

1. Bring the pouch to room temperature before opening it. Remove the test from the sealed pouch and use it within one hour.
2. Remove the collector from the sealed pouch and collect oral fluid specimen as follows:
   Important: Place the tongue against the upper and lower jaws and roots to enrich the oral fluid before oral fluid collection.
   Insert the sponge end into the mouth, actively swab around the gums on both sides of the mouth and under the tongue and chew the sponge tenderly, place the sponge end under the tongue for a total of **2-3 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.
3. Remove the collector from the mouth. Place saturated oral fluid collector into collection tube and press sponge fully against the strainer to collect oral fluid. Discard the collector. Snap the cap shut on the Collection tube.
4. 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. Avoid trapping air bubbles in the specimen well. Place screw cap on the collection tube. Wait for the flow to appear in the test windows and start the timer.
5. Read the test results at **3-10 minutes.**
   If all lines are clearly visible at 3 minutes or sooner，then the test can be interpreted as negative and discarded. If any lines not visible at 3 minutes, then the test should be re-read at 10 minutes.
6. Apply the security seal over screw cap and send to the laboratory for confirmation if necessary.



INTERPRETATION OF RESULTS

(Please refer to the illustration above)

NEGATIVE:* **Two lines appear**. One colored line should be in the control region (C), and another apparent colored 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 colored 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 colored 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

1. 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.
2. 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.
3. 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.
4. Test does not distinguish between drugs of abuse and certain medications.
5. 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
COT Rapid Test Cassette	Results	Positive	Negative	
	Positive	131	3	134
	Negative	1	95	96
Total Results		132	98	230
% Agreement		99.2%	96.9%	98.3%

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
Acetophenetidin	5,5-Diphenylhydantoin	Maprotiline	l-Phenylephrine
Acetylsalicylic acid	Disopyramide	Meperidine	β-Phenylethylamine
N-Acetylprocainamide	Doxylamine	Mephentermine	Phenylpropanolamine (d,l-norephedrine)
Albumin	Ecgonine	Meprobamate	(±) Phenylpropanolamine
Aminopyrine	Ecgonine methylester	Methadone	Prednisolone
Amitriptyline	EDDP	d-Methamphetamine	Prednisone
Amobarbital	Efavirenz (Sustiva)	l-Methamphetamine	5β-Pregnane-3α, 17α, 21-triol
Amoxapine	EMDP	Methaqualone	Procaine
Amoxicillin	Ephedrine	Methoxyphenamine	Promazine
l-Amphetamine	l-Ephedrine	(-) 3,4-Methylenedioxy-amphetamine (MDA)	Promethazine
Ampicillin	(±)-Epinephrine	(+) 3,4 Methylendioxy-methamphetamine (MDMA)	d,l-Propanolol
Apomorphine	l-Epinephrine	Methylphenidate	d-Propoxyphene
l-Ascorbic acid	Erythromycin	Methyprylon	d-Pseudoephedrine
Aspartame	β-Estradiol	Methaqualone	Quinacrine
Atropine	Estrone-3-sulfate	Metoprolol	Quinidine
Benzilic acid	Ethanol (Ethyl alcohol)	Morphine sulfate	Quinine
Benzoic acid	Ethyl-p-aminobenzoate	Morphine-3-β-D-glucuronide	Ranitidine
Benzoylecgonine	Etodolac	Nalidixic acid	Riboflavin
Benzphetamine	Famprofazone	Nalorphine	Salicylic acid
Bilirubin	Fenfluramine	Naloxone	Secobarbital
(±)-Brompheniramine	Fenoprofen	Naltrexone	Serotonin (5-hydroxytryptamine)
Buspirone	Fentanyl	Methyprylon	Sodium chloride
Caffeine	Fluoxetine	Metoprolol	Sulfamethazine
Cannabidiol	Furosemide	Nimesulide	Sulindac
Cannabinol	Gentisic acid	Norcodein	Temazepam
Chloral hydrate	d (+) Glucose	Morphine sulfate	Tetracycline
Chloramphenicol	Guaiacol glyceryl ether	α-Naphthaleneacetic acid	Tetrahydrocortisone, 3-acetate
Chlordiazepoxide	Guaiacol glyceryl ether carbamate	Norethindrone	Tetrahydrozoline
Chloroquine	Hemoglobin	Normorphine	Thebaine
Chlorothiazide	Hydralazine	d-Norpropoxyphene	Theophylline
(+)-Chlorpheniramine	Hydrochlorothiazide	Noscapine	Thiamine
(±)-Chlorpheniramine	Hydrocodone	d,l-Octopamine	Thioridazine (chlorpromazine)
Chlorpromazine	Hydrocortisone	Orphenadrine	l-Thyroxine
Chlorprothixene	Hydromorphone	Oxalic acid	Tolbutamide
Cholesterol	p-Hydroxyamphetamine	Oxazepam	cis-Tramadol
Cimetidine	o-Hydroxyhippuric acid	Oxolinic acid	Trazodone
Clomipramine	p-Hydroxymethamphetamine	Oxycodone	Triamterene
Clonidine	p-Hydroxynorephedrine	Oxymetazoline	Trifluoperazine
Cocaine	Hydroxyzine	Oxymorphone	Trimethobenzamide
Codeine	3-Hydroxytyramine	Papaverine	Trimethoprim
Cortisone	Ibuprofen	Pemoline	Trimipramine
Creatinine	Imipramine	Penicillin-G	Tryptamine
Cyclobarbital	Iproniazid	Pentazocine	d,l-Tryptophan
Cyclobenzaprine	l-Isoproterenol	Pentobarbital	Tyramine
Deoxycorticosterone	Isoxsuprine	Perphenazine	d,l-Tyrosine
(-) Deoxyephedrine	Kanamycin	Phencyclidine	Uric acid
R (-) Deprenyl	Ketamine	Phenelzine	Verapamil
Dextromethorphan	Ketoprofen	Pheniramine	Zomepirac
Diazepam	Labetalol	Phenobarbital	
Diclofenac	Levorphanol	Phenothiazine	
Dicyclomine	Lidocaine		
Diflunisal	Lindane (hexachlorocyclohexane)		
Digoxin			

Index of Symbols

⚠	Attention, see instructions for use	Σ	Tests per kit	EC REP	Authorized Representative
IVD	For in vitro diagnostic use only	⌛	Use by	2	Do not reuse
2°C 30°C	Store between 2-30°C	LOT	Lot Number	REF	Catalog #
	Do not use if package is damaged		Manufacturer		Consult Instructions for Use

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