

# Amazewell™

## D-Pen™ Mini COT Oral Fluid Test

### INSTRUCTIONS FOR USE

PLEASE READ ALL INFORMATION IN THE INSTRUCTIONS FOR USE BEFORE USING THE TEST!

**REF** See Box Label

#### INTENDED USE

D-Pen™ Mini COT Oral Fluid Test is a rapid oral fluid screening test. It's a lateral flow, one-step immunoassay for the qualitative detection of cotinine in human oral fluid at the cut-off level of 50 ng/mL.

This assay provides a qualitative, preliminary test result. A more specific analytical method must be used in order to obtain a confirmed result. Gas Chromatography/Mass spectrometry (GC/MS) or Liquid Chromatography/Tandem Mass Spectrometry (LC/MS-MS) are the preferred confirmatory methods. Professional judgment should be applied to any drug test result, particularly when preliminary positive results are indicated. *It is intended for forensic use only.*

#### SUMMARY

Cotinine is the first-stage metabolite of nicotine, a toxic alkaloid that stimulates the autonomic ganglia and central nervous system 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. Aside from tobacco, nicotine is also commercially available as the active ingredient in smoking replacement therapies such as nicotine gum, transdermal patches and nasal sprays. Regardless of whether nicotine in a donor was derived from tobacco use or through a nicotine-replacement therapy, if the metabolite cotinine is present in sufficient concentration, the test result will be positive. Although nicotine is excreted in saliva, the relatively short half-life of the drug makes it an unreliable marker for tobacco use. Cotinine, however, demonstrates a substantially longer half-life than nicotine, bears a high correlation with plasma cotinine levels and has been found to be the best marker for smoking status compared with saliva nicotine measurements, breath carbon monoxide testing and plasma thiocyanate testing.

#### PRINCIPLE OF THE PROCEDURE

D-Pen™ Mini COT Oral Fluid Test is a competitive immunoassay that is used to screen for the presence of cotinine in oral fluid. It is a chromatographic absorbent device in which cotinine in a sample competitively combined to a limited number of antibody-dye conjugate binding sites.

When the absorbent tip of the test device is immersed into the oral fluid sample, the sample is absorbed into the device by capillary action, mixes with the antibody-dye conjugate, and flows across the pre-coated membrane. When sample drug levels are zero or below the target cut off (the detection sensitivity of the test), antibody-dye conjugate binds to the drug-protein conjugate immobilized in the Test Region (T) of the device. This produces a colored Test line that, regardless of its intensity, indicates a negative result.

When sample drug levels are at or above the target cutoff, the free drug in the sample binds to the antibody-dye conjugate preventing the antibody-dye conjugate from binding to the drug-protein conjugate immobilized in the Test Region (T) of the device. This prevents the development of a distinct colored band in the test region, indicating a potentially positive result.

To serve as a procedure control, a colored line will appear at the Control Region (C), if the test has been performed properly.

#### WARNINGS AND PRECAUTIONS

1. For external use only. Do not swallow.
2. Discard after first use. The test cannot be used more than once.
3. Do not use test kit beyond expiration date.
4. Do not use the kit if the pouch is punctured or not well sealed.
5. Keep out of the reach of children.
6. Do not read result after 10 minutes.
7. The used test device should be discarded according to local regulations.

#### STORAGE AND STABILITY

1. Store at 35°F - 86°F (2°C - 30°C) in the sealed pouch up to the expiration date.
2. Keep away from direct sunlight, moisture and heat.
3. **DO NOT FREEZE.**
4. Preferably open the pouch only shortly before the test.

#### MATERIALS AND COMPONENTS

##### REAGENTS AND MATERIALS SUPPLIED

- D-Pen™ Mini COT Oral Fluid Test
- Instructions for use

##### MATERIALS REQUIRED BUT NOT PROVIDED

- Timer or stopwatch

#### SAMPLE COLLECTION AND TEST PROCEDURE

Please read the instructions carefully before testing.

1. Allow the test device to equilibrate to room temperature (59°F - 86°F / 15°C - 30°C).
2. Remove the test device from the foil pouch by tearing at the notch. Hold the grip and remove the cap to expose the absorbent tip.
3. Place the absorbent tip horizontally into the mouth, then swab the inside of the mouth and tongue to collect oral fluid.
4. Take the absorbent tip out from the mouth when the purple color moves across the result window in the center of the test device.
5. Read results at 5 minutes. Do not read after 10 minutes.



#### NOTE:

\*When sampling, gently hold it in mouth and let saliva naturally adsorb on the absorbent tip.

\*Do not eat, drink, or smoke for at least 30 minutes prior to sample collection.

\*Any saliva specimen is appropriate for testing but the saliva specimen collected in the morning, before mouth rinsed, eating or drinking, is recommended.

#### INTERPRETATION OF TEST RESULTS

##### Preliminary Positive (+)

A color band is visible in the control region. No color band appears in the test region. It indicates the concentration of cotinine is equal to or higher than the detection limit.

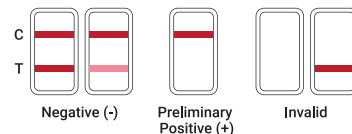
##### Negative (-)

A color band is visible in the control region and the test region. It indicates that the concentration of cotinine is zero or below the detection limit.

##### Invalid

If a color band is not visible in the control region, the test is invalid. Another test should be run to re-evaluate the specimen. If test still fails, please contact the distributor or manufacturer with the lot number.

NOTE: There is no meaning attributed to line color intensity or width.



#### QUALITY CONTROL

Though there is an internal procedural control line in the test device of Control region, the use of external controls is strongly recommended as good laboratory testing practice to confirm the test procedure and to verify proper test performance. Positive and negative control should give the expected results. When testing the positive and negative control, the same assay procedure should be adopted.

#### LIMITATIONS OF PROCEDURE

1. The test 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 preferred confirmatory methods.
2. A positive test result does not indicate the concentration of drug in the specimen or the route of administration.
3. A negative result may not necessarily indicate a drug-free specimen. Drug may be present in the specimen below the cutoff level of the assay.

## PERFORMANCE CHARACTERISTICS

### A. Analytical Sensitivity

D-Pen™ Mini COT Oral Fluid Test has set the screen cut-off for positive specimens at 50 ng/mL for cotinine as a calibrator. The test device has been proved to detect above cut-off of cotinine in oral fluid at 5 minutes.

### B. Analytical Specificity

The following table lists the concentration of compounds above which the D-Pen™ Mini COT Oral Fluid Test identified positive results at a read time of 5 minutes.

Compound	Concentration (ng/mL)
<b>Cotinine (COT)</b>	
(-) Cotinine	50
S(-)-Nicotine	5,000

### C. Interfering substances

A study was conducted to determine the cross-reactivity of the test with the following compounds. The following compounds show no cross-reactivity when tested with D-Pen™ Mini COT Oral Fluid Test at a concentration up to 100 µg/mL.

Aminopyrine	Lofexidine
Amoxicillin	Loperamide
Ampicillin	Maprotiline
Apomorphine	Meperidine
Aspartame	Meprobamate
Aspirin	Methadone
Atropine	Methoxyphenamine
Benadryl	Morphine-3-β-D-glucuronide
Benzilic acid	N-Acetylprocainamide
Benzoic acid	Nalidixic acid
Benzylecgonine	Naloxone
Bilirubin	Naltrexone
Cannabidiol	Naproxen
Captopril	Niacinamide
Chloralhydrate	Nifedipine
Chloramphenicol	Nitroglycerin
Chlorothiazide	Norcodeine
Chlorpromazine	Norethindrone
Chloroquine	Noscapine
Cholesterol	O-Hydroxyhippuric acid

Clarithromycin	Omeprazole
Clonidine	Oxalic acid
Codeine	Oxazepam
(-) Cotinine (except COT test)	Oxolinic acid
Cortisone	Oxymetazoline
Creatinine	Papaverine
Deoxycorticosterone	Penicillin V Potassium
Dextromethorphan	Penicillin-G
Diazepam	Pentobarbital
Diclofenac	Perphenazine
Diflunisal	Phencyclidine
Digoxin	Phenelzine
Diphenhydramine	Phenytoin
D L-Tryptophan	Pholcodine
D,L-Isoproterenol	Prednisone
D,L-Octopamine	Procaine
DL-Propranolol	Propranolol HCl
DL-Tyrosine	Quinine
D-Norpropoxyphene	Ranitidine
D-Propoxyphene	Ranitidine HCl
D-Pseudoephedrine	Salicylic acid
Dopamine HCl	Secobarbital
Doxepine	Serotonin (5-Hydroxytyramine)
Doxylamine	Sulfamethazine
Ecgonine methyl ester	Sulindac
β-Estradiol	Tetrahydrocortisone3-(β-Dglucuronide)
Erythromycin	Tetrahydrocortisone, 3-acetate
Estrogen	Tetrahydrozoline
Fenoprofen	Thiamine
Furosemide	Thioridazine
Gentisic acid	Triamterene
Hydralazine	Trifluoperazine
Hydrochlorothiazide	Trimethoprim
Hydrocodone	Tyramine
3-Hydroxytyramine	Uric acid
Hydrocortisone	Venlafaxine HCl

Ibuprofen	Verapamil
Isoxsuprine	Sertraline Hydrochloride
Ketamine	Zomepirac
Ketoprofen	

## BIBLIOGRAPHY OF SUGGESTED READING

- Moolchan, E., et al, "Saliva and Plasma Testing for Drugs of Abuse: Comparison of the Disposition and Pharmacological Effects of Cocaine", Addiction Research Center, IRP, NIDA, NIH, Baltimore, MD. As presented at the SOFT-TIAFT meeting October 1998.
- Kim, I, et al, "Plasma and oral fluid pharmacokinetics and pharmacodynamics after oral codeine administration", Clin Chem, 2002 Sept.; 48 (9), pp 1486-96.
- Schramm, W. et al, "Drugs of Abuse in Saliva: A Review," J Anal Tox, 1992 Jan-Feb; 16 (1), pp 1-9.
- McCarron, MM, et al, "Detection of Phencyclidin Usage by Radioimmunoassay of Saliva," J Anal Tox. 1984 Sep-Oct.; 8 (5), pp 197-201

## ASSISTANCE

Call toll-free (888) 695-5248 (Monday – Friday 9:00 am – 5:00 pm, CST) or email to [support@dochekusa.com](mailto:support@dochekusa.com).

## INDEX OF SYMBOL



Consult instructions for use



Keep dry



Store at 35°F - 86°F (2°C - 30°C)



Keep away from sunlight



Use-by date



Catalogue number



Batch code



Do not reuse



Do not use if package is damaged

## Manufactured for:

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## Made in China

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