T-Dip® Cotinine (COT) Urine Test Panel

Catalogue No. See Box label

The T-Dip® Cotinine (COT) Urine Test Panel is a competitive binding, lateral flow immunochromatographic assay for qualitative and simultaneous detection of Cotinine (COT) in human urine with below cutoff concentration and approximate detection time:

Drug (Identifier)	Calibrator	Cut-off Level	Minimum Detection Time	Maximum Detection Time
Cotinine (COT)	Cotinine	200 ng/mL	2-8 hours	1-7 days

It is intended for forensic use only.

The test is not intended to distinguish between prescription use or abuse of these drugs. Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly in evaluating a preliminary positive result.

The test provides only preliminary test results. To obtain a confirmed analytical result, a more specific alternate chemical method must be used. Chromatography/Mass Spectrometry (GC/MS) or Liquid Chromatography/Tandem Mass Spectrometry (LC/MS-MS) is the recommended confirmatory method.

WARNINGS AND PRECAUTIONS

1. The test kit is for external use only. Do not swallow.
2. Discard after first use. The test kit cannot be used more than once.
3. Do not use the test kit beyond expiration date.
4. Do not use the test kit if the pouch is punctured or not sealed.
5. Keep out of the reach of children.
6. Do not read after 5 minutes.

CONTENT OF THE KIT

1. Test devices, one test in one pouch. One pouch containing a test and a desiccant. The desiccant is for storage purposes only, and is not used in the test procedures.
2. Package Insert

MATERIAL REQUIRED BUT NOT PROVIDED

1. Urine collection cup
2. Timer or clock

STORAGE AND STABILITY

Store at 4ºC-30ºC (39ºF-86ºF) in the sealed pouch up to the expiration date.
Keep away from direct sunlight, moisture and heat.
DO NOT FREEZE.

SPECIMEN COLLECTION

WHEN TO COLLECT URINE FOR THE TEST?

The minimum detection time of Cotinine (COT) is 2-8 hours, urine specimens may be collected 2-8 hours after the suspected drug use.

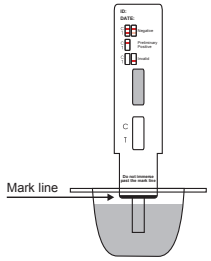
HOW TO COLLECT URINE?

Instruct the donor to void directly into the urine collection cup. Wipe off any splashes or spills that may be on the outside of the cup. It is recommended to wear gloves when handling the urine collection cup with urine specimen.

TEST PROCEDURE

Test should be performed at room temperature 18ºC-30ºC (65ºF-86ºF).

1. Remove the test device from the foil pouch by tearing at the notch. Use it as soon as possible.
2. Hold one side of the device with one hand. Use the other hand to pull out the cap and expose the absorbent end.
3. Immerse the absorbent end into the urine specimen for approximately 10 seconds. **Make sure that the urine level is not above the marked line printed on the front of the device.**
4. Re-cap the device and lay it flat on a clean, dry, non-absorbent surface.
5. Read the result at 5 minutes. **Do not read after 5 minutes.**



Note: Results after more than 5 minutes may be not accurate and should not be read.

READING THE RESULTS

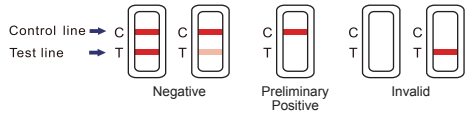
Negative (-)
A colored band is visible in each Control Region (C) and the appropriate Test Region (T). It indicates that the concentration of the corresponding drug of that specific test zone is zero or below the detection limit of the test.

Preliminary Positive (+)
A colored band is visible in each Control Region (C). No colored band appears in the appropriate Test Region (T). It indicates a preliminary positive result for the corresponding drug of that specific test zone.

Invalid
If a colored band is not visible in each of the Control Region (C) or a colored band is only visible in each of the Test Region (T), the test is invalid. Another test should be run to re-evaluate the specimen. If test still fails, please contact the distributor with the lot number.

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

The preliminary positive test result does not always mean that a person took illegal drugs. The negative test result does not always mean that a person did not take illegal drugs. There could be a number of factors that affect the reliability of drug tests.



What Is the False Positive Test?

The definition of the false positive test would be an instance where a substance is identified incorrectly by the T-Dip® Cotinine (COT) Urine Test Panel. The most common causes of the false positive test are cross reactants. Certain foods and medicines, diet plan drugs and nutritional supplements may cause the false positive test result.

What Is the False Negative Test?

The definition of the false negative test is that the initial drug is present but isn't detected by the T-Dip® Cotinine (COT) Urine Test Panel. If the specimen is diluted, or the specimen is adulterated that may cause false negative result.

If suspect someone is taking drugs but get the negative test results, please test again at another time.

TEST LIMITATIONS

1. This test kit has been developed for testing urine samples only. No other fluids have been evaluated. DO NOT use it to test anything other than urine.
2. Adulterated urine samples may produce false results. Strong oxidizing agents such as bleach (hypochlorite) can oxidize drug analytes. If a specimen is suspected of being adulterated, obtain a new specimen.
3. It is possible that technical or procedural errors, as well as other interfering substances in the urine specimen may cause false results.
4. This test is a qualitative screening assay. It is not designed to determine the quantitative concentration of drug or the level of intoxication.

SUMMARY

Cotinine is an alkaloid found in tobacco and is also a major metabolite of Nicotine, which produces stimulation of the autonomic ganglia and central nervous system when in humans. Nicotine is found in tobacco products such as cigarettes, tobacco chew, and nicotine patches or gums. It is an addictive substance and is poisonous in a large amount. In addition to addiction, some of the other substances within tobacco products, such as carbon monoxide or tar, are dangerous to the body and can lead to medical conditions such as emphysema, lung cancer, and heart disease. In a 24-hour urine, approximately 5% of a nicotine dose is excreted as unchanged drug with 10% as cotinine and 35% as hydroxycotinine; the concentrations of other metabolites are believed to account for less than 5%. While Cotinine is thought to be an inactive metabolite, its elimination profile is more stable than that of Nicotine which is largely urine PH dependent. Cotinine is stable in body fluids and has a relatively long half-life of approximately 17 hours, and is typically detectable for several days (up to one week) after the use of tobacco, therefore the detection of Cotinine is less dependent on the time of sampling than that of Nicotine.

Nicotine and Cotinine are rapidly eliminated by the kidney; the window of detection for cotinine in urine at a cutoff level of 200 ng/mL is expected to be up to 2~3 days after nicotine use.

PRINCIPLE

The T-Dip® Cotinine (COT) Urine Test Panel is a competitive immunoassay that is used to screen for the presence of drugs in urine. It is chromatographic absorbent device in which drugs in a specimen competitively combined to a limited number of drug monoclonal antibody (mouse) conjugate binding sites.

When the absorbent end is immersed into urine specimen, the urine is absorbed into the device by capillary action, mixes with the respective drug monoclonal antibody conjugate, and flows across the pre-coated membrane. When sample drug levels are zero or below the target cutoff (the detection sensitivity of the test), respective drug monoclonal antibody conjugate binds to the respective 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 respective drug monoclonal antibody conjugate preventing the respective drug monoclonal antibody conjugate from binding to the respective 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 (T), 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. This control line should always appear regardless of the presence of drug or metabolite. If the control line does not appear the test device should be discarded.

QUALITY CONTROL

Users should follow the appropriate federal, state, and local guidelines concerning the frequency of assaying external quality control materials. Even though there is an internal procedural control line in the test device in the Control Region (C), 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 controls should give the expected results. When testing the positive and negative controls, the same assay procedure should be adopted. External Control (positive and negative) should be run with each new lot of test received, each new shipment, each new operator and monthly to determine that tests are working properly.

PERFORMANCE CHARACTERISTICS

Accuracy

Eighty clinical urine specimens were analyzed by GC/MS or LC-MS/MS and by the T-Dip® Cotinine (COT) Urine Test Panel. Each test was read by three viewers. Samples were divided by concentration into five categories: Drug Free, Less than Half the Cutoff, Near Cutoff Negative, Near Cutoff Positive, and High Positive. Results were as follows:

Result		Drug Free	Less than Half the Cutoff	Near Cutoff Negative (Between 50% below the cutoff and the cutoff)	Near Cutoff Positive (Between the cutoff and 50% above the cutoff)	High Positive (Greater than 50% above the cutoff)	% Agreement with GC/MS or LC/MS
Viewer A	+	0	0	2	29	10	97.5%
	-	10	10	18	1	0	95%
Viewer B	+	0	0	1	28	10	95%
	-	10	10	19	2	0	97.5%
Viewer C	+	0	0	2	29	10	97.5%
	-	10	10	18	1	0	95%

Precision and Sensitivity

To investigate the precision and sensitivity, each drug sample was analyzed at the following concentrations: cutoff -100%, cutoff -75%, cutoff -50%, cutoff -25%, cutoff, cutoff +25%, cutoff +50%, cutoff +75% and the cutoff +100%. All concentrations were confirmed with GC/MS or LC-MS/MS. The study was used three different lots of the T-Dip® Cotinine (COT) Urine Test Panel. The data are summarized below:

Approximate Concentration of Sample (ng/mL)	Number of Determinations per Lot	Results (Negative/Positive)		
		Lot 1	Lot 2	Lot 3
0	50	50/0	50/0	50/0
50	50	50/0	50/0	50/0
100	50	50/0	50/0	50/0
150	50	48/2	49/1	47/3
200	50	6/44	4/46	5/45
250	50	4/46	3/47	2/48
300	50	0/50	0/50	0/50
350	50	0/50	0/50	0/50
400	50	0/50	0/50	0/50

Specificity and Cross Reactivity

To test the specificity of the test, the test device was used to test various drugs, drug metabolites and other components of the same class that are likely to be present in urine. All the components were added to drug-free normal human urine. The following structurally related compounds produced positive results with the test when tested at levels equal to or greater than theconcentrations listed below.

Substance	Concentration (ng/mL)
Cotinine (COT)	
Cotinine	200

Effect of Urinary Specific Gravity

The results demonstrate that the urinary specific gravity range of 1.000~1.035 does not affect the test results.

Effect of Urinary pH

The results demonstrate that the range of urinary pH from 4 to 9 does not interfere with the performance of test.

Interfering Substances

The following compounds were added to drug-free urine, urine with drug concentration 25% below the cutoff, and urine with drug concentration 25% above the cutoff for the corresponding T-Dip® Cotinine (COT) Urine Test Panel. All potential interferents were added at a concentration of 100 µg/mL. None of the urine samples showed any deviation from the expected results.

3-Hydroxytyramine
Acetaminophen
Acetophenetidin
Acetylsalicylic Acid
Acyclovir
Afrin
Albumin
Aminophylline
Aminopyrine
Amiodarone Hydrochloride
Amlodipine Mesylate
Amoxicillin
Ampicillin
Apomorphine
Aripiprazole
Aspartame
Atomoxetine
Atorvastatin Calcium
Atropine
Benzilic Acid
Benzoic Acid
Bilirubin
Captopril
Carbamazepine
Cefradine
Cephalexin
Chloral Hydrate
Chloramphenicol
Chloroquine
Chlorpheniramine
Cholesterol
Ciprofloxacin Hydrochloride
Citalopram
Clarithromycin
Clonidine
Clopidogrel Hydrogen Sulphate
Clozapine
d,l-Propranolol
d,l-Octopamine
d,l-Tyrosine
Deoxycorticosterone
Dextromethorphan
Diclofenac
Dicyclomine
Diflunisal
Digoxin
Diphenhydramine
Dirithromycin
d-Norpropoxyphene
Domperidone
D-Pseudoephedrine
Duloxetine
Enalapril Maleate
Epinephrine Hydrochloride
Erythromycin
Esomeprazole Magnesium
Ethanol
Fenofibrate
Fenoprofen
Fentanyl Citrate
Fluoxetine Hydrochloride
Fluvoxamine
Furosemide
Gabapentin
Gentisic Acid
Glibenclamide
Gliclazide
Glipizide
Glucose
Haloperidol
Hemoglobin
Ibuprofen
Isosorbide Dinitrate
Isoxsuprine
Ketamine
Ketoconazole
Ketoprofen
Kratom powder
Labetalol
Lamotrigine
Levofloxacin Hydrochloride
Levonorgestrel
Levothyroxine Sodium
Lidocaine Hydrochloride
Lisinopril
Lithium Carbonate
Liverite
Loperamide
Loratadine
Magnesium
Maprotiline
Meperidine
Meprobamate
Metoprolol Tartrate
Mifepristone
Minocycline
Mirtazapine
Montelukast Sodium
Mosapride Citrate
N-acetylprocainamide
Nalidixic Acid
Naproxen
Niacinamide
Nifedipine
Norethindrone
O-Hydroxyhippuric Acid
Olanzapine
Omeprazole
Ondansetron
Oxalic Acid
Oxolinic Acid
Oxymetazoline
Paliperidone
Pantoprazole
Papaverine
Paroxetine Hydrochloride
Penfluridol
Penicillin-G
Penicillin V Potassium
Phenelzine
Pioglitazone Hydrochloride
Piracetam
Pravastatin Sodium
Prednisone
Promethazine
Propylthiouracil
Quetiapine Fumarate
Quinine
Ranitidine
Rifampicin
Risperidone
Salicylic Acid
Serotonin
Sertraline Hydrochloride
Sildenafil Citrate
Simvastatin
Sodium Valproate
Spironolactone
Sulfamethazine
Sulindac
Tetracycline
Tetrahydrocortisone 3-acetate
Tetrahydrocortisone-(β-D-glucuronide)
Tetrahydrozoline
Thiamine
Thioridazine
Topiramate
Trazodone Hydrochloride
Triamterene
Trifluoperazine
Trimethoprim
Uric Acid
Valproate
Verapamil
Vitamin B2
Vitamin C
Ecgonine Methyl Ester
Effexor
Nikethamide
Nimodipine
β-Estradiol

ASSISTANCE

If you have any question regarding to the use of this product, please call our Toll Free Number 1-888-444-3657 (9:30 a.m. to 5:00 p.m. CDT M-F).

BIBLIOGRAPHY OF SUGGESTED READING

Baselt, R.C. Disposition of Toxic Drugs and Chemicals in Man. Biomedical Publications, Davis, CA, 1982.
Ellenhorn, M.J. and Barceloux, D. G Medical Toxicology. Elservier Science Publishing Company, Inc., New York, 1988.
Gilman, A. G., and Goodman, L. S. The Pharmacological Fluids, in Martin WR (ed): Drug Addiction I, New York, Spring – Verlag, 1977.
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Hawwks RL, CN Chiang. Urine Testing for drugs of Abuse. National Institute for Drug Abuse (NIDA), Research Monography 73, 1986.
Hofmann F.E., A Handbook on Drug and Alcohol Abuse: The Biomedical Aspects, New York, Oxford University Press, 1983.
McBay, A. J. Clin. Chem. 33,33B-40B, 1987.

ADDITIONAL INFORMATION AND RESOURCES

The following list of organizations may be helpful to you for counseling support and resources. These groups also have an Internet address which can be accessed for additional information.
National Clearinghouse for Alcohol and Drug Information www.health.org 1-800-729-6686
Center for Substance Abuse Treatment www.health.org 1-800-662-HELP
The National Council on Alcoholism and Drug Dependence www.ncadd.org
1-800-NCA-CALL
American Council for Drug Education (ACDE) www.acde.org 1-800-488-DRUG

INDEX OF SYMBOLS


Keep away from sunlight

Store between 4°C - 30°C (39°F - 86°F)


Keep dry


Do not re-use

Manufactured by Guangzhou Wondfo Biotech Co., LTD
No.8 Lizhishan Road, Science City, Luogang District
Guangzhou, Guangdong, P.R. China 510663

Made in China

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