

DrugCheck® Dip Drug Test

The **DrugCheck® Dip Drug Test** is an immunochromatographic assay for the qualitative detection of Cotinine in human urine at a cutoff concentration indicated in the table below.

The test may yield preliminary positive results when prescription drugs are ingested at prescribed doses. It is not intended to distinguish between prescription use and abuse of any drug. There are no uniformly recognized cutoff concentration levels for any drug in urine. The test provides only preliminary test results. A more specific alternative 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 exercised with any drug of abuse test result, particularly when the preliminary result is positive.

For in vitro diagnostic use and for professional testing use only.

WHAT IS DRUGCHECK® DIP DRUG TEST?

The **DrugCheck® Dip Drug Test** is a rapid test for qualitative detection of Cotinine in human urine. The **DrugCheck® Dip Drug Test** yields a positive result when drug and/or its metabolite in urine is at or exceeds its cutoff concentration.

WHAT IS THE CUT-OFF VALUE?

Drug Test	Drug (Identifier)	Cut-off
Cotinine (COT)	Cotinine	200 ng/mL

PRINCIPLE

The **DrugCheck® Dip Drug Test** is an immunoassay. During testing, a urine specimen migrates upward on the test strip. A drug-positive urine specimen will not generate a colored line in the specific test line region of the strip, while a drug-negative urine specimen will generate a line in the test line region. A colored line will always appear at the control line region, indicating that proper volume of specimen has been added.

The test contains a membrane strip coated with drug-protein conjugates (purified bovine albumin) on the test line, a goat polyclonal antibody against gold-protein conjugate at the control line, and a dye pad which contains colloidal gold particles coated with mouse monoclonal antibody specific to individual drug on the list indicated in the table above.

WARNINGS AND PRECAUTIONS

- For in vitro diagnostic use and for professional testing use only.
- For external use only.
- For single use. Discard after first use.
- Do not use the test if the pouch is punctured or not well sealed.
- Do not use after expiration date.
- Keep out of the reach of children.
- The used dip test and urine specimen should be discarded according to federal, state and local regulations.

CONTENT OF THE PACKAGE

Included in package:	Not included in package:
- User Instruction	- Watch, Timer or Clock
- Dip Test (inside foil pouch)	- Collection Cup

STORAGE AND STABILITY

Store as packaged in the sealed pouch at 4°C - 30°C (39°F - 86°F). The test is stable through the expiration date printed on the sealed pouch. The dip test must remain in the sealed pouch until use. Keep away from direct sunlight, moisture and heat. DO NOT FREEZE. Do not use beyond the expiration date.

WHEN TO COLLECT URINE FOR THE TEST?

You can use urine from any time of the day. The minimum detection time varies for different drugs.

HOW TO COLLECT URINE?

- When you are ready to begin, remove the dip test from the sealed foil pouch.
- Notice the colored tape on each strip indicates the name of the drug you are testing for.
- Fill the collection cup with a fresh urine sample. Do not over-fill.

HOW TO DO THE TEST?

For Single Dip Strip

- Insert the test strip into the urine sample for 10 to 15 seconds. DO NOT let the urine sample touch the conjugate pad on the strip, this could cause inconclusive drug test results. Place the test on a flat surface.
- Wait for 5 minutes (start timing immediately after dip is taken out of the urine sample). Read result at 5 minutes. DO NOT READ RESULT AFTER 5 MINUTES.

For Single Dip Cassette

- Remove the cap from the dip test. Insert the exposed test strip into the urine sample for 10 to 15 seconds. DO NOT let the urine sample touch the plastic device, this could cause inconclusive drug test results.
- Insert the cap firmly back onto the dip test and lay it on a flat surface.
- Wait for 5 minutes (start timing immediately after dip test is taken out of the urine sample). Read result at 5 minutes. DO NOT READ RESULT AFTER 5 MINUTES.

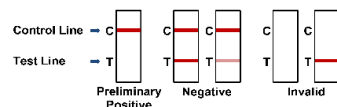
Note: Results after more than 5 minutes may not be accurate and should not be read.

READING THE RESULTS

Preliminary Positive (+): If a line appears in the C - Control area but NO line appears in the T - Test area, then it indicates a Preliminary Positive result for the corresponding drug.

Negative (-): If a line appears in both the C - Control and T - Test area, then it indicates a Negative result for the corresponding drug regardless of how dark or light the line may appear.

Invalid: If at 5 minutes, NO line appears in the C - Control area, then the results are Invalid. In such case, retest with a new dip test.



Note: Each test strip needs to be looked at individually. Each line may vary in color and darkness or the rate at which the line appears. (DO NOT compare lines within the same test strip or between different test strips).

A positive test result does not always mean a person took illegal drugs and a negative test result does not always mean a person did not take illegal drugs. There are a number of factors that influence the reliability of drug tests. Certain drugs of abuse tests are more accurate than others.

IMPORTANT: The result you obtained is called preliminary for a reason. The sample must be tested by a laboratory in order to determine if a drug of abuse is actually present.

WHAT IS A FALSE POSITIVE TEST?

The definition of a false positive test would be an instance where the test result from the **DrugCheck® Dip Drug Test** is positive, even though the initial target drug is not present in the sample. The most common causes of a false positive test are cross reactants. Certain foods and medicines, diet plan drugs and nutritional supplements may also cause a false positive test result with this product.

WHAT IS A FALSE NEGATIVE TEST?

The definition of a false negative test is that the initial target drug is present but is not detected by the **DrugCheck® Dip Drug Test**. If the sample is diluted, or if the sample is tainted or contaminated with a substance this could cause false negative results.

TEST LIMITATIONS

- The **DrugCheck® Dip Drug 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 the preferred confirmatory method.
- There is a possibility that interfering substances in the urine specimen may cause erroneous results.
- Substances, such as bleach and/or alum, in urine specimens may produce erroneous results.
- A positive result does not indicate intoxication, the concentration of drug in the urine, or the route of drug administration.
- A negative result may not necessarily indicate drug-free urine. Negative results can be obtained when drug is present but below the cutoff level of the test.
- Test does not distinguish between drugs of abuse and certain medications.
- A positive test result may be obtained from certain foods or food supplements.

QUALITY CONTROL

If you work in a laboratory, you should perform quality control testing and you should read this section.

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.

Control standards are not supplied with this kit. However, it is recommended that positive and negative controls be tested as good laboratory practice to confirm the test procedure and to verify proper test performance. Quality control testing should be done with each new lot and each new shipment. It should be done every thirty days to check storage. Please contact our Technical Support at 507-526-3951 for controls that work with the dip test.

PERFORMANCE CHARACTERISTICS

Accuracy

In the comparison study, the **DrugCheck® Dip Drug Test** was compared to a GC/MS reference method to determine its accuracy. Clinical urine samples were collected for Cotinine. Clinical specimens were quantified by GC/MS analysis before testing. The following results are tabulated from these clinical studies:

Accuracy – Cotinine

Analyte	Positive	Negative
Negative Samples	0	20
Near Cut-off Negative Samples [between 50% of cut-off and cut-off]	1	19
Near Cut-off Positive Samples [between cutoff and 150% of cut-off]	19	1
Positive Samples [>150% of cut-off]	20	0
Agreement with GC/MS	98%	98%

Overall Agreement with GC/MS is 96%.

Reproducibility

Reproducibility studies were carried out using commercially available stock solutions of the drug analyte listed. Dilutions were made from the stock solution of Cotinine to the concentrations specified in the following table. The results are listed in the following table.

Approximate Concentration of Sample (ng/mL)	Number of Determinations	Result	Precision
0	60	60 negative	>99%
100	60	60 negative	>99%
400	60	60 positive	>99%

Analytical Sensitivity

A drug-free urine pool was spiked with drugs at concentrations listed. The results are summarized below.

Drug concentration Cut-off Range	n	Cotinine	
		-	+
0% Cut-off	90	90	0
-50% Cut-off	90	90	0
-25% Cut-off	90	90	0
Cut-off	90	63	27
+25% Cut-off	90	40	50
+50% Cut-off	90	16	74
2X Cut-off	90	0	90

Analytical Specificity

The following table lists the concentration of compounds (ng/mL) that were detected positive in urine by the **DrugCheck® Dip Drug Test** at a read time of 5 minutes.

Cotinine	Result
(-)-Cotinine, Cutoff = 200 ng/mL)	Positive at 200 ng/mL
(-)-Nicotine	Positive at 6,250 ng/mL

EFFECT OF URINARY SPECIFIC GRAVITY

Urine samples of normal, high, and low specific gravity ranges (1.000-1.035) were spiked with drugs at 25% below and 25% above cut-off levels respectively. The **DrugCheck® Dip Drug Test** was tested using twelve drug-free urine and spiked urine samples. The results demonstrate that varying ranges of urinary specific gravity do not affect the test results.

EFFECT OF URINARY PH

The pH of an aliquot of negative urine pool was adjusted to pH ranges of 4.0 - 9.0 and spiked with drugs at 25% below and 25% above cut-off levels. The spiked, pH-adjusted urine was tested with the **DrugCheck® Dip Drug Test**. The results demonstrate that varying ranges of pH do not interfere with the performance of the test.

INTERFERENCE

A study was conducted to determine the cross-reactivity of the test with compounds in either drug-free urine or drug positive urine containing Cofinine. The following compounds show no cross-reactivity when tested with the **DrugCheck® Dip Drug Test** at concentrations of 100 µg/mL.

Acebutolol Hydrochloride	D-Glucuronic acid	Penicillin G Sodium salt
Acepromazine-d6 hydrochloride	Glutethimide	Phenelzine sulfate salt
	Guaifenesin	Phenobarbital
Acetaminophen	Hemoglobin porcine	Phentermine HCL
N-Acetylprocainamide	Heroin hydrochloride	Phenylethylamine
Acetophenetidin	Hippuric Acid	L-phenylephrine
Alprazolam	Hydralazine hydrochloride	Phenylpropanolamine hydrochloride
Alphenal	Hydromorphone	
Amoxicillin	Hydrocodone	Prednisolone
Ampicillin	α-Hydroxyhippuric acid	Prednisone Acetate Tablets
Amitriptyline Hydrochloride Tablets	21-Hydroxy progesterone	
	p-Hydroxy-methamphetamine	Procaine HCL
S(+)-Amphetamine		Promazine hydrochloride
R(-)-Amphetamine	Hydrocortisone	Promethazine
Amobarbital	Hydrochlorothiazide	Propoxyphene, d-
(±)Amphetamine	-4-Hydroxyamphetamine HCL	Propranolol Hydrochloride
R(-)-Apomorphine Hydrochloride		Pseudoephedrine
	Ibuprofen	Phendimetrazine
Aprobarbital	Imipramine	Phenytoin
Aspirin	Ipiazid	Quinine
Aspartame	Isoxsuprine hydrochloride	Quinidine
L-Ascorbic Acid	Isoproterenol Hydrochloride Injection	Quinacrine
Atropine		Ranitidine Hydrochloride Tablets
6-Acetylmorphine	Ketamine hydrochloride	
Acetylsalicylic acid	Ketoprofen	Nortriptyline Hydrochloride
Benzphetamine	Emetine dihydrochloride hydrate	Salicylic Acid
Benzilic acid		Secobarbital
Benzoylcegonine	Ephedrine-(+/-) hydrochloride	Serotonin
SS Benzoic Acid		Noroxymorphone HCL
Bilirubin, Mixed Isomers	(-)-Ephedrine HCL	Nylidrin hydrochloride
Brompheniramine maleate	[1R,2S] (-) Ephedrine	Norfentanyl
Buprenorphine	Erythromycin	(±)-Octopamine HCL
Buspirone hydrochloride	Eserine	Oxalic Acid
Butalbital	Estazolam	Oxolinic Acid
Butabarbital	β-Estradiol	Oxycodone
Cannabidiol	(±)-EDDP	Oxymetazoline
Cannabinol	Ethyl-p-aminobenzoate	Papaverine
Caffeine	JWH-018 pantanoic acid	(±)-Octopamine HCL
Cetirizine Hydrochloride	JWH-073 butanoic acid	Sertraline HCl
Chlordiazepoxide HCL	Labetalol Hydrochloride	Sulfamethazine, min 99%
Chlorothiazide	Levorphanol	Sulindac
Chloroquine	Loperamide Hydrochloride	Temazepam
Chlorpheniramine Maleate	Lorazepam	Terfenadine

Chlorpromazine Hydrochloride Tablets	Maprotiline hydrochloride	Terbutaline
Chloramphenicol ChloralHydrate	(±)-MDEA	Tetraethylthiuram disulfide
	Meperidine	Tetrahydrocannabinol, Delta-8-(-)-delta-8-THC
Cholesterol	Meprobamate	Tetracycline
Chlorothiazide	Methamphetamine hydrochloride	Tetrahydrocortisone 3-(β-D-glucuronide (-)-delta-9-THC)
Clomipramine		
Clonazepam	(±)Methadone	
Clonidine hydrochloride	S(+)-D-methamphetamine	(+/-)11-Hydroxy-delta-9-THC
Clozapine	L-methamphetamine	
(-) Cotinine	Methylphenidate	(-)-11-nor-9-Carboxy-delta9-THC
Cocaethylene	(±)-MDMA	
Cocaine Hydrochloride	(±)-MDPV	Thebaine
Codeine	Methyprylon	Theophylline
Cortisone	Morphine	Thioridazine
Creatinine	Morphine-3β-D-glucuronide	Thiamine, (Vitamin B1 Tablets) HCL
Cyclobenzotribital		
Citalopram hydrobromide	Morphine sulfate salt solution	DL-Thyroxine
Dextromethorphan		Tolbutamide
Desipramine	Nalidixic acid	Tramadol
Diazepam	Nalorphine hydrochloride	Triamterene
Diclofenac Sodium salt	Naproxen	Trimipramine
Dicyclomine	Naloxone	Tryptamine
Digoxin	Naltrexone hydrochloride	Trifluoperazine dihydrochloride
4-Dimethylaminoantipyrine	Nicotinamide (vitamin B3)	
Dihydrocodeine HCL	Nimesulide	DL-Tryptophan
5,5-Diphenylhydantoin	Nifedipine	Triazolam
Diphenhydramine	Norcodeine	
Dopamine	Nordoxepin hydrochloride	Trans-2-phenylcyclopropylamine hydrochloride
Doxylamine	Norfloracin Capsule	
Ecgonine methylester	Norethisterone Tablets	D/L-Tyrosine
Ecgonine HCL	d-Norpropoxyphene maleate salt	Tyramine
Efavirenz		Uric Acid
Ethylone	Noscapine	Verapamil Hydrochloride
EthylMorphine	PCP	Valproic acid
Fenoprofen	Pentobarbital	Zomepirac
Furosemide	Pentazocine	
Gentisic acid	Perphenazine	

BIBLIOGRAPHY OF SUGGESTED READING

- Stewart DJ, Inaba T, Lucassen M, Kalow W. Clin. Pharmacol. Ther. April 1979; 25 ed: 464, 264-8.
- Ambre J. J. Anal. Toxicol. 1985; 9:241.
- Hawks RL, CN Chiang. Urine Testing for Drugs of Abuse. National Institute for Drug Abuse (NIDA), Research Monograph 73, 1986.

ADDITIONAL INFORMATION AND REFERENCES

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

SYMBOLS

	Use-By Date		Manufacturer
	Catalogue Number		Temperature Limit
	Do Not Use if Package is Damaged		Do Not Re-Use
	Keep Away from Sunlight		Consult Instructions for Use
	Keep Dry		Caution
	Batch Code		In Vitro Diagnostic Medical Device
	Authorized representative in the European Community		Contains Sufficient for <n> Tests

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