

## DrugCheck® Dip Drug Test

The **DrugCheck® Dip Drug Test** is an immunochromatographic assay for the qualitative detection of Phencyclidine 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 Phencyclidine 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
Phencyclidine (PCP)	Phencyclidine	25 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. 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.

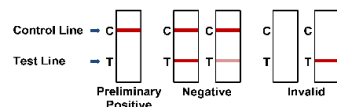
Note: Results after more than 5 minutes may not be accurate and should not be read.

### 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 Phencyclidine. Clinical specimens were quantified by GC/MS analysis before testing. The following results are tabulated from these clinical studies:

#### Accuracy – Phencyclidine

Viewer A:

Result	Drug-free	Less than half the cutoff Concentration by GC/MS analysis	Near cutoff negative (Between 50% below the cutoff and the cutoff concentration)	Near cutoff positive (Between the cutoff and 50% above the cutoff concentration)	High positive (Greater than 50% above the cutoff concentration)
Positive	0	0	1	13	26
Negative	10	10	19	1	0

% agreement among positives is 97.5%

% agreement among negatives is 97.5%

Viewer B:

Result	Drug-free	Less than half the cutoff Concentration by GC/MS analysis	Near cutoff negative (Between 50% below the cutoff and the cutoff concentration)	Near cutoff positive (Between the cutoff and 50% above the cutoff concentration)	High positive (Greater than 50% above the cutoff concentration)
Positive	0	0	1	13	26
Negative	10	10	19	1	0

% agreement among positives is 97.5%

% agreement among negatives is 97.5%

Viewer C:

Result	Drug-free	Less than half the cutoff Concentration by GC/MS analysis	Near cutoff negative (Between 50% below the cutoff and the cutoff concentration)	Near cutoff positive (Between the cutoff and 50% above the cutoff concentration)	High positive (Greater than 50% above the cutoff concentration)
Positive	0	0	0	12	26
Negative	10	10	20	2	0

% agreement among positives is 95%

% agreement among negatives is 100%

From the results of the above tables, the total results are shown as below for Phencyclidine:

The average positive agreement is 96.7%.

The average negative agreement is 98.3%.

### Precision and Sensitivity – Phencyclidine

Lot 1

Approximate Concentration of Sample (ng/mL)	Number of Determinations	Results Negative/Positive
0	50	50/0
6.3	50	50/0
12.5	50	50/0
18.8	50	50/0
25	50	3/47
31.3	50	0/50
37.5	50	0/50
43.8	50	0/50
50	50	0/50

Lot 2

Approximate Concentration of Sample (ng/mL)	Number of Determinations	Results Negative/Positive
0	50	50/0
6.3	50	50/0
12.5	50	50/0
18.8	50	50/0
25	50	2/48
31.3	50	0/50
37.5	50	0/50
43.8	50	0/50
50	50	0/50

Lot 3

Approximate Concentration of Sample (ng/mL)	Number of Determinations	Results Negative/Positive
0	50	50/0
6.3	50	50/0
12.5	50	50/0
18.8	50	50/0
25	50	2/48
31.3	50	0/50
37.5	50	0/50
43.8	50	0/50
50	50	0/50

### 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.

Phencyclidine	Result
(Phencyclidine, Cutoff = 25 ng/mL)	Positive at 25 ng/mL
Phencyclidine Morpholine	Positive at 625 ng/mL
4-Hydroxyphencyclidine	Positive at 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 Phencyclidine. The following compounds show no cross-reactivity when tested with the **DrugCheck® Dip Drug Test** at concentrations of 100 µg/mL.

Acetaminophen	β-Estradiol	Oxycodone
Acetophenetidin	Estrone-3-Sulfate	Oxymetazoline
N-Acetylprocainamide	Ethyl-p-Aminobenzoate	Papaverine
Acetylsalicylic Acid	Fenoprofen	Penicillin-G
Aminopyrine	Furosemide	Pentazocine
Amitriptyline	Gentisic Acid	Hydrochloride
Amobarbital	Hemoglobin	Pentobarbital
Amoxicillin	Hydralazine	Perphenazine
Ampicillin	Hydrochlorothiazide	Phenelzine
Ascorbic Acid	Hydrocodone	Phenobarbital
DL-Amphetamine	Hydrocortisone	Phentermine
Apomorphine Acid	o-Hydroxyhippuric	L-Phenylephrine
Aspartame	p-Hydroxy-methamphetamine	β-Phenylethylamine
Atropine	3-Hydroxytyramine	Phenylpropanolamine
Benzilic Acid	Ibuprofen	Prednisolone
Benzoic Acid	Imipramine	Prednisone
Benzoylcegonine	Iproniazid	Procaine
Benzphetamine	(±)-Isoproterenol	Promazine
Bilirubin	Isoxsuprine	Promethazine
Brompheniramine	Ketamine	DL-Propranolol
Caffeine	Ketoprofen	D-Propoxyphene
Cannabidiol	Labetalol	D-Pseudoephedrine
Cannabinol	Loperamide	Quinidine
Chloral Hydrate	Maprotiline	Quinine
Chloramphenicol	Meperidine	Ranitidine
Chlordiazepoxide	Meprobamate	Salicylic Acid
Chlorothiazide	Methadone	Secobarbital
(±)-Chlorpheniramine	Methoxyphenamine	Serotonin (5-Hydroxytyramine)
Chlorpromazine	(±)-3,4-Methylenedioxy-amphetamine	Sulfamethazine
Chloroquine	(±)-3,4-Methylenedioxy-methamphetamine	Sulindac
Cholesterol		Temazepam
Clomipramine		Tetracycline
Clonidine		Tetrahydrocortisone 3-(β-D-Glucuronide)
Cocaine Hydrochloride		Tetrahydrozoline
Codeine		Thiamine
Cortisone		Thioridazine
(-)-Cotinine		DL-Tyrosine
Creatinine		Tolbutamide
Deoxycorticosterone		Triamterene
Dextromethorphan		Trifluoperazine
Diazepam		Trimethoprim
Diclofenac		Trimipramine
Diffunisal		Tryptamine
Digoxin		DL-Tryptophan
Diphenhydramine		Tyramine
Doxylamine		
Ecgonine Hydrochloride		
Ecgonine Methyl Ester		
(-)-ψ-Ephedrine		
Erythromycin		

### 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](http://www.health.org) 1-800-729-6686


Center for Substance Abuse Treatment [www.health.org](http://www.health.org) 1-800-662-HELP


The National Council on Alcoholism and Drug Dependence [www.ncadd.org](http://www.ncadd.org) 1-800-NCA-CALL

American Council for Drug Education (ACDE) [www.acde.org](http://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

 CareHeath America Corporation  
dba Express Diagnostics Int'l, Inc.  
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