PCP Rapid Test Cassette (Urine) Package Insert

REF DPC-102
English

A rapid, test for the qualitative detection of Phencyclidine in human urine.
For medical and other professional in vitro diagnostic use only.

INTENDED USE

The PCP Rapid Test Cassette (Urine) is a rapid chromatographic immunoassay for the detection of Phencyclidine in urine at a cut-off concentration of 25 ng/mL. This test will detect other related compounds, please refer to the Analytical Specificity table in this package insert.

This assay provides only a 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

Phencyclidine, also known as PCP, is a hallucinogen that was first marketed as a surgical anesthetic in the 1950's. It was removed from the market because patients receiving it became delirious and experienced hallucinations.

Phencyclidine is used in powder, capsule, and tablet form. The powder is either snorted or smoked after mixing it with marijuana or vegetable matter. PCP is most commonly administered by inhalation but can be used intravenously, intra-nasally, and orally. After low doses, the user thinks and acts swiftly and experiences mood swings from euphoria to depression. Self-injurious behavior is one of the devastating effects of PCP.

PCP can be found in urine within 4 to 6 hours after use and will remain in urine for 7 to 14 days, depending on factors such as metabolic rate, user's age, weight, activity, and diet. PCP is excreted in the urine as unchanged drug (4% to 19%) and conjugated metabolites (25% to 30%).[1]

PRINCIPLE

The PCP Rapid Test Cassette (Urine) is an immunoassay based on the principle of competitive binding. Drugs that may be present in the urine specimen compete against the drug conjugate for binding sites on the antibody.

During testing, a urine specimen migrates upward by capillary action. Phencyclidine, if present in the urine specimen below 25 ng/mL, will not saturate the binding sites of the antibody in the test. The antibody coated particles will then be captured by immobilized Phencyclidine 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 Phencyclidine level exceeds 25 ng/mL because it will saturate all the binding sites of anti-Phencyclidine antibodies.

A drug-positive urine specimen will not generate a colored line in the test line region because of drug competition, while a drug-negative urine 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-Phencyclidine antibody-coupled particles and Phencyclidine-protein conjugate. A goat antibody is employed in the control line system.

PRECAUTIONS

- For medical and other professional in vitro diagnostic use only. Do not use after the expiration date.
- The test should remain in the sealed pouch until use.
- All specimens should be considered potentially hazardous and handled in the same manner as an infectious agent.
- The used test should be discarded according to local regulations.

STORAGE AND STABILITY

Store as packaged at room temperature or refrigerated (2-30°C). The test is stable through the expiration date printed on the sealed pouch or label of the closed canister. The test must remain in the sealed pouch or closed canister until use. **DO NOT FREEZE**. Do not use beyond the expiration date.

SPECIMEN COLLECTION AND PREPARATION

Urine Assay

The urine specimen must be collected in a clean and dry container. Urine collected at any time of the day may be used. Urine specimens exhibiting visible particles should be centrifuged, filtered, or allowed to settle to obtain a clear specimen for testing.

Specimen Storage

Urine specimens may be stored at 2-8°C for up to 48 hours prior to testing. For prolonged storage, specimens may be frozen and stored below -20°C. Frozen specimens should be thawed and mixed before testing.

MATERIALS

Materials Provided

• Test Cassettes • Droppers • Package insert

Materials Required But Not Provided

• Specimen collection container • Timer

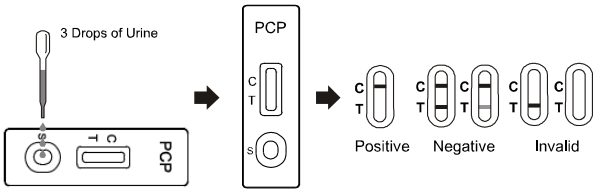
DIRECTIONS FOR USE

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

1. Bring the pouch to room temperature before opening it. Remove the test cassette from the sealed pouch and use it within one hour.

2. Place the test cassette on a clean and level surface. Hold the dropper vertically and transfer **3 full drops of urine** (approx. 120 µL) to the specimen well (S) of the test cassette, and then start the timer. Avoid trapping air bubbles in the specimen well (S). See the illustration below.

3. Wait for the color line(s) to appear. **The result should be read at 5 minutes.** Do not interpret the result after 10 minutes.



INTERPRETATION OF RESULTS

(Please refer to the illustration above)

NEGATIVE:* Two lines appear. One colored line should be in the control line region (C), and another apparent colored line should be in the test line region (T). This negative result indicates that the Phencyclidine concentration is below the detectable level (25 ng/mL).

***NOTE:** The shade of color in the test line region (T) may vary, but it should be considered negative whenever there is even a faint colored line.

POSITIVE: One colored line appears in the control line region (C). No line appears in the test line region (T). This positive result indicates that the Phencyclidine concentration exceeds the detectable level (25 ng/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. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

QUALITY CONTROL

A procedural control is included in the test. A colored line appearing in the control line 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 testing practice to confirm the test procedure and to verify proper test performance.

LIMITATIONS

1. The PCP Rapid Test Cassette (Urine) 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.[2,3]
2. It is possible that technical or procedural errors, as well as other interfering substances in the urine specimen may cause erroneous results.
3. Adulterants, such as bleach and/or alum, in urine specimens may produce erroneous results regardless of the analytical method used. If adulteration is suspected, the test should be repeated with another urine specimen.
4. A positive result indicates presence of the drug or its metabolites but does not indicate level of intoxication, administration route or concentration in urine.
5. A negative result may not necessarily indicate drug-free urine. Negative results can be obtained when drug is present but below the cut-off level of the test.
6. Test does not distinguish between drugs of abuse and certain medications.

EXPECTED VALUES

This negative result indicates that the Phencyclidine concentration is below the detectable level of 25ng/ml. Positive result means the concentration of Phencyclidine is above the level of 25ng/ml. The PCP Rapid Test Cassette has a sensitivity of 25ng/ml

PERFORMANCE CHARACTERISTICS

Accuracy

A side-by-side comparison was conducted using PCP Rapid Test Cassette and a commercially available PCP rapid test. Testing was performed on 95 clinical specimens previously collected from subjects present for Drug Screen Testing. The following results were tabulated:

Method		Other PCP Rapid Test		Total Results
PCP Rapid Test Cassette	Results	Positive	Negative	
	Positive	38	0	38
	Negative	0	57	57
Total Results		38	57	95
% Agreement		>99.9%	>99.9%	>99.9%

A side-by-side comparison was conducted using The PCP Rapid Test Cassette and GC/MS at the cut-off of 25ng/mL. Testing was performed on 250 clinical specimens previously collected from subjects present for Drug Screen Testing. The following results were tabulated:

Method		GC/MS		Total Results
PCP Rapid Test Cassette	Results	Positive	Negative	
	Positive	85	5	90
	Negative	7	153	160
Total Results		92	158	250
% Agreement		92.4%	96.8%	95.2%

Analytical Sensitivity

A drug-free urine pool was spiked with Phencyclidine at the following concentrations: 0 ng/mL, 12.5 ng/mL, 18.75 ng/mL, 25 ng/mL, 31.25 ng/mL, 37.5 ng/mL and 75 ng/mL. The result demonstrates >99% accuracy at 50% above and 50% below the cut-off concentration. The data are summarized below:

Phencyclidine Concentration (ng/mL)	Percent of Cut-off	n	Visual Result	
			Negative	Positive
0	0	30	30	0
12.5	-50%	30	30	0
18.75	-25%	30	26	4
25	Cut-off	30	15	15
31.25	+25%	30	3	27
37.5	+50%	30	0	30
75	3X	30	0	30

Analytical Specificity

The following table lists compounds that are positively detected in urine by the PCP Rapid Test Cassette (Urine) at 5 minutes.

Compound	Concentration (ng/mL)
4-Hydroxyphencyclidine	12,500
Phencyclidine	25

Precision

A study was conducted at three hospitals by laypersons using three different lots of product to demonstrate the within run, between run and between operator precision. An identical panel of coded specimens containing, according to GC/MS, no Phencyclidine, 25% Phencyclidine above and below the cut-off, and 50% Phencyclidine above and below the 25 ng/mL cut-off was provided to each site. The following results were tabulated:

Phencyclidine Concentration (ng/mL)	n per Site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	10	10	0	10	0	10	0
12.5	10	10	0	10	0	10	0
18.75	10	8	2	9	1	9	1
31.25	10	1	9	1	9	1	9
37.5	10	0	10	0	10	0	10

Effect of Urinary Specific Gravity

Fifteen urine specimens with normal, high, and low specific gravity ranges were spiked with 12.5 ng/mL and 37.5 ng/mL of Phencyclidine. The PCP Rapid Test Cassette (Urine) was tested in duplicate using the fifteen neat and spiked urine specimens. The results demonstrate that varying ranges of urinary specific gravity do not affect the test results.

Effect of Urinary pH

The pH of an aliquoted negative urine pool was adjusted to a pH range of 5 to 9 in 1 pH unit increments and spiked with Phencyclidine to 12.5 ng/mL and 37.5 ng/mL. The spiked, pH-adjusted urine was tested with the PCP Rapid Test Cassette (Urine) in duplicate. The results demonstrate that varying ranges of pH do not interfere with the performance of the test.

Cross-Reactivity

A study was conducted to determine the cross-reactivity of the test with compounds in either drug-free urine or Phencyclidine positive urine. The following compounds show no cross-reactivity when tested with the PCP Rapid Test Cassette (Urine) at a concentration of 100 µg/mL.

Non Cross-Reacting Compounds

Acetaminophen	Creatinine	Meperidine	Prednisolone
Acetophenetidin	Deoxycorticosterone	Meprobamate	Prednisone
N-Acetylprocainamide	Dextromethorphan	Methadone	Procaine
Acetylsalicylic acid	Diazepam	Methoxyphenamine	Promazine
Aminopyrine	Diclofenac	(+) 3,4-Methylenedioxy-	Promethazine
Amitryptyline	Diflunisal	Amphetamine	D,L-Propanolol
Amobarbital	Digoxin	(+) 3,4-Methylenedioxy-	D-Propoxyphene
Amoxicillin	Diphenhydramine	methamphetamine	D-Pseudoephedrine
Ampicillin	Doxylamine	Morphine-3-	Quinidine
L-Ascorbic acid	Ecgonine hydrochloride	β-D glucuronide	Quinine
D,L-Amphetamine	Ecgonine methylester	Morphine Sulfate	Ranitidine
Apomorphine	(-)-ψ-Ephedrine	Nalidixic acid	Salicylic acid
Aspartame	Erythromycin	Naloxone	Secobarbital
Atropine	β-Estradiol	Naltrexone	Serotonin
Benzilic acid	Estrone-3-sulfate	Naproxen	(5-Hydroxytyramine)

Benzoic acid	Ethyl-p-aminobenzoate	Niacinamide	Sulfamethazine
Benzoylecgonine	Fenoprofen	Nifedipine	Sulindac
Benzphetamine	Furosemide	Norcodein	Temazepam
Bilirubin	Gentisic acid	Norethindrone	Tetracycline
(±) – Brompheniramine	Hemoglobin	D-Norpropoxyphene	Tetrahydrocortisone,
Caffeine	Hydralazine	Noscapine	3-Aacetate
Cannabidiol	Hydrochlorothiazide	D,L-Octopamine	Tetrahydrocortisone
Cannabinol	Hydrocodone	Oxalic acid	3-(β-D glucuronide)
Chloralhydrate	Hydrocortisone	Oxazepam	Tetrahydrozoline
Chloramphenicol	O-Hydroxyhippuric acid	Oxolinic acid	Thiamine
Chlordiazepoxide	p-Hydroxy-	Oxycodone	Thioridazine
Chlorothiazide	Methamphetamine	Oxymetazoline	D, L-Tyrosine
(±) Chlorpheniramine	3-Hydroxytyramine	Papaverine	Tolbutamide
Chlorpromazine	Ibuprofen	Penicillin-G	Triamterene
Chlorquine	Imipramine	Pentazocine hydrochloride	Trifluoperazine
Cholesterol	Iproniazid	Pentobarbital	Trimethoprim
Clomipramine	(±) - Isoproterenol	Perphenazine	Trimipramine
Clonidine	Isoxsuprine	Phenelzine	Tryptamine
Cocaine hydrochloride	Ketamine	Phenobarbital	D, L-Tryptophan
Codeine	Ketoprofen	Phentermine	Tyramine
Cortisone	Labetalol	L-Phenylephrine	Uric acid
(-) Cotinine	Loperamide	β-Phenylethylamine	Verapamil
	Maprotiline	Phenylpropanolamine	Zomepirac

BIBLIOGRAPHY

1. Robert DeCresce. Drug Testing in the Workplace. BNA Books. 1989; 114
2. Baselt RC. Disposition of Toxic Drugs and Chemicals in Man. 2nd Ed. Biomedical Publ., Davis, CA. 1982; 488
3. Hawks RL, CN Chiang. *Urine Testing for Drugs of Abuse*. National Institute for Drug Abuse (NIDA), Research Monograph 73, 1986

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

Manufacturer

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