

One Step Phencyclidine (PCP) Test Device (Urine)

A rapid, one step test for the qualitative detection of Phencyclidine in human urine.

IVD For *in vitro* diagnostic use only

2  30°C
Store at 2-30 °C

INTENDED USE

The PCP One Step Phencyclidine Test Device (Urine) is a lateral flow chromatographic immunoassay for the detection of Phencyclidine in urine at a cut-off concentration of 25 ng/mL.

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.

INTRODUCTION

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, intranasally, 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. Phencyclidine is excreted in the urine as unchanged drug (4% to 19%) and conjugated metabolites (25% to 30%).¹

PRINCIPLE

The PCP One Step Phencyclidine Test Device (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 device. 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.

MATERIALS

Materials Provided

- Test devices (contain mouse monoclonal anti-Phencyclidine-coupled particles and Phencyclidine-protein conjugate. A goat antibody is employed in the control line system).
- Disposable droppers
- Package insert

Materials Required But Not Provided

- Specimen collection container
- Timer

PRECAUTIONS

- For *in vitro* diagnostic use only. Do not use after the expiration date.
- The test device 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 test device should be discarded according to federal, state and local regulations.

STORAGE AND STABILITY

- The kit can be stored at room temperature or refrigerated (2-30°C).
- The test Cassette is stable through the expiration date printed on the label on the sealed pouch.
- The test Cassette must remain in the sealed pouch until use. Do not freeze.

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.

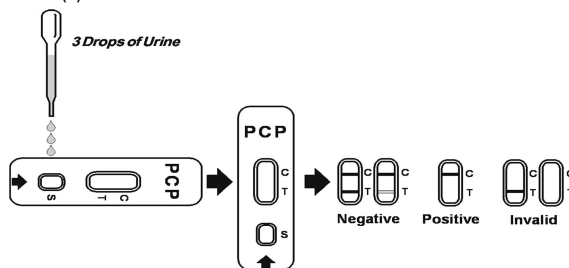
Specimen Storage

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

PROCEDURE

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

1. Bring the pouch to room temperature before opening it. Remove the test device from the sealed pouch and use it as soon as possible.
2. Place the test device on a clean and level surface. Hold the dropper vertically and **transfer 3 full drops of urine** (approx. 100µl) to the specimen well (S) of the test device, and then start the timer. Avoid trapping air bubbles in the specimen well (S). See the illustration.



3. Wait for the red 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 illustration)

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

NOTE:

The shade of red in the test region (T) may vary, but it should be considered negative whenever there is even a faint pink line.

POSITIVE: One red line appears in the control region (C). No line appears in the test 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 device. 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 red 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 testing practice to confirm the test procedure and to verify proper test performance.

LIMITATIONS

1. The PCP One Step Phencyclidine Test Device (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.

PERFORMANCE CHARACTERISTICS

Accuracy

A side-by-side comparison was conducted using the PCP One Step Phencyclidine Test Device (Urine) and a leading commercially available PCP rapid test. Testing was performed on 212 clinical specimens. Ten percent of the specimens employed were either at -25% or +25% level of the cut-off concentration of 25 ng/mL Phencyclidine. Presumptive positive results were confirmed by GC/MS. The following results were tabulated:

Method		Other PCP Rapid Test		Total Results
PCP One Step Test Device	Results	Positive	Negative	
	Positive	55	0	55
	Negative	2	155	157
Total Results		57	155	212
% Agreement with this Rapid Test Kit		97%	100%	99%

When compared at 25 ng/mL cut-off with GC/MS, the following results were tabulated:

Method		GC/MS		Total Results
PCP One Step Test Device	Results	Positive	Negative	
	Positive	50	5	55
	Negative	0	157	157
Total Results		50	162	212
% Agreement with GC/MS Analysis		100%	97%	98%

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 and 37.5 ng/mL. The result demonstrates >99% accuracy at 50% above and 50% below the cut-off concentration. The data are summarized below:

PCP 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	11	19
31.25	+25%	30	8	22
37.5	+50%	30	0	30

Analytical Specificity

The following table lists the compound that is positively detected in urine by the PCP One Step Phencyclidine Test Device (Urine) at 5 minutes.

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

Precision

A study was conducted at 3 physicians' offices by untrained operators using 3 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 results are tabulated:

Phencyclidine conc. (ng/mL)	n per site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	15	15	0	15	0	15	0
12.5	15	15	0	15	0	15	0
18.75	15	14	1	12	3	14	1
31.25	15	1	14	6	9	6	9
37.5	15	1	14	0	15	0	15

Effect of Urinary Specific Gravity

Fifteen (15) urine specimens with specific gravity ranging from 1.001 to 1.032 were spiked with 12.5 ng/mL and 37.5 ng/mL of Phencyclidine respectively. The PCP One Step Phencyclidine Test Device (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 37.5ng/mL. The spiked, pH-adjusted urine was tested with the PCP One Step Phencyclidine Test Device (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 One Step Phencyclidine Test Device (Urine) at a concentration of 100 µg/mL.


Non Cross-Reacting Compounds












Acetaminophen	β-Estradiol	Oxymetazoline
Acetophenetidin	Estrone-3-sulfate	Papaverine
N-Acetylprocainamide	Ethyl-p-aminobenzoate	Penicillin-G
Acetylsalicylic acid	Fenoprofen	Pentazocine hydrochloride
Aminopyrine	Furosemide	Pentobarbital
Amitypyline	Gentisic acid	Perphenazine
Amobarbital	Hemoglobin	Phenelzine
Amoxicillin	Hydralazine	Phenobarbital
Ampicillin	Hydrochlorothiazide	Phentermine
L-Ascorbic acid	Hydrocodone	L-Phenylephrine
D,L-Amphetamine	Hydrocortisone	β-Phenylethylamine
Apomorphine	O-Hydroxyhippuric acid	Phenylpropanolamine
Aspartame	p-Hydroxy-methamphetamine	Prednisolone
Atropine	mine	Prednisone
Benzilic acid	3-Hydroxytyramine	Procaine
Benzoic acid	Ibuprofen	Promazine
Benzoylcegonine	Imipramine	Promethazine
Benzphetamine	lproniazid	D,L-Propranolol
Bilirubin	(±) - Isoproterenol	D-Propoxyphene
(±) -Brompheniramine	Isoxsuprine	D-Pseudoephedrine
Caffeine	Ketamine	Quinidine
Cannabidiol	Ketoprofen	Quinine
Cannabinol	Labetalol	Ranitidine
Chloralhydrate	Loperamide	Salicylic acid
Chloramphenicol	Maprotiline	Secobarbital
Chlordiazepoxide	Meperidine	Serotonin
Chlorothiazide	Meprobamate	(5-Hydroxytyramine)
(±) Chlorpheniramine	Methadone	Sulfamethazine
Chlorpromazine	Methoxyphenamine	Sulindac
Chlorquine	(+) 3,4-Methylenedioxy-amphetamine	Temazepam
Cholesterol	(+) 3,4-Methylenedioxy-methamphetamine	Tetracycline
Clomipramine		Tetrahydrocortisone, 3 acetate
Clonidine		Tetrahydrocortisone 3 (β-D glucuronide)
Cocaine hydrochloride	Morphine-3-β-D glucuronide	
Codeine		
Cortisone	Morphine Sulfate	Tetrahydrozoline
(-) Cotinine	Nalidixic acid	Thiamine
Creatinine	Naloxone	Thioridazine
Deoxycorticosterone	Naltrexone	D, L-Tyrosine
Dextromethorphan	Naproxen	Tolbutamide
Diazepam	Niacinamide	Triamterene
Diclofenac	Nifedipine	Trifluoperazine
Diflunisal	Norcodein	Trimethoprim

Digoxin	Norethindrone	Trimipramine
Diphenhydramine	D-Norpropoxyphene	Tryptamine
Doxylamine	Noscapine	D, L-Tryptophan
Ecgonine hydrochloride	D,L-Octopamine	Tyramine
Ecgonine methylester	Oxalic acid	Uric acid
(-) Y Ephedrine	Oxazepam	Verapamil
Erythromycin	Oxolinic acid	Zomepirac
	Oxycodone	

REFERENCES

1. Robert DeCresce. *Drug Testing in the workplace*. 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

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	Product Reference No.		For in-vitro diagnostic use.
	Caution.		Store at
	Read product insert before use.		Number of tests in the pack.
	Lot (batch) number.		Manufacturer.
	Expiry date.		Manufacturer telephone number.
	Manufacturer fax number.		