

BIOMERICA

One Step

Phencyclidine Test Strip (Urine)

Package Insert

REF 1189-S

A rapid, one step test for the qualitative detection of Phencyclidine in human urine.
For professional *in vitro* diagnostic use only.

INTENDED USE

The PCP One Step Phencyclidine Test Strip (Urine) is a lateral flow 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 One Step Phencyclidine Test Strip (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 strip. 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 strip contains mouse monoclonal anti-Phencyclidine antibody-coupled particles and Phencyclidine-protein conjugate. A goat antibody is employed in the control line system.

PRECAUTIONS

- For professional *in vitro* diagnostic use only. Do not use after the expiration date.
- The test strip 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 strip should be discarded according to local regulations.

STORAGE AND STABILITY

Store as packaged in the sealed pouch either at room temperature or refrigerated (2-30°C). The test strip is stable through the expiration date printed on the sealed pouch. The test strip must remain in the sealed pouch 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.

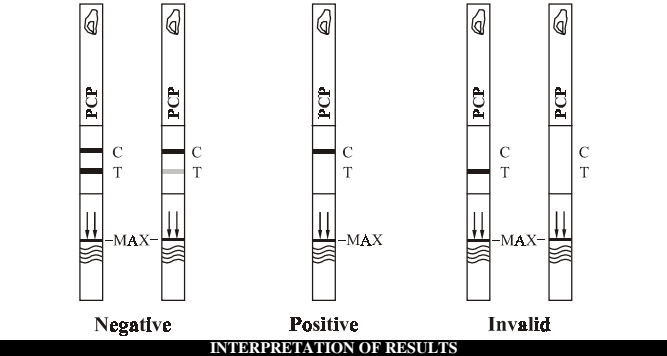
MATERIALS

- Materials Provided**
- Test strips
 - Package insert
- Materials Required But Not Provided**
- Specimen collection container
 - Timer

DIRECTIONS FOR USE

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

- Bring the pouch to room temperature before opening it. Remove the test strip from the sealed pouch and use it as soon as possible.
- With arrows pointing toward the urine specimen, **immerse the test strip vertically in the urine specimen for at least 10-15 seconds.** Do not pass the maximum line (MAX) on the test strip when immersing the strip. See the illustration below.
- Place the test strip on a non-absorbent flat surface, start the timer and wait for the colored line(s) to appear. **Read results 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 strip. 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

- The PCP One Step Phencyclidine Test Strip (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}
- It is possible that technical or procedural errors, as well as other interfering substances in the urine specimen may cause erroneous results.
- 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.
- A positive result indicates presence of the drug or its metabolites but does not indicate level of intoxication, administration route or concentration in urine.
- 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.
- 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 Strip (Urine) and a leading commercially available PCP rapid test. Testing was performed on 212 clinical specimens previously collected from subjects present for Drug Screen Testing. 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
	Positive	Negative	
PCP One Step Test Strip	56	0	56
	1	155	156
Total Results	57	155	212
% Agreement	98%	>99%	99%

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

Method	GC/MS		Total Results
	Positive	Negative	
PCP One Step Test Strip	50	5	55
	0	157	157
Total Results	50	162	212
% Agreement	>99%	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:

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	19	11
25	Cut-off	30	16	14
31.25	+25%	30	6	24
37.5	+50%	30	0	30

Analytical Specificity

The following table lists compounds that are positively detected in urine by the PCP One Step Phencyclidine Test Strip (Urine) at 5 minutes.

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

Precision
A study was conducted at three physicians' offices by untrained operators 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	15	15	0	15	0	15	0
12.5	15	15	0	14	1	14	1
18.75	15	11	4	13	2	10	5
31.25	15	8	7	5	10	1	14
37.5	15	4	11	0	15	0	15

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 One Step Phencyclidine Test Strip (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 One Step Phencyclidine Test Strip (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 Strip (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-Amphetamine	Promethazine
Amitriptyline	Diffusal	(+) 3,4-Methylenedioxy-methamphetamine	D,L-Propanolol
Amobarbital	Digoxin	Morphine-3-β-D glucuronide	D-Propoxyphene
Amoxicillin	Diphenhydramine	Oxalic acid	D-Pseudoephedrine
Ampicillin	Doxylamine	Oxolonic acid	Quinidine
Ascorbic acid	Ecgonine hydrochloride	Oxycodone	Quinine
D,L-Amphetamine	Ecgonine methylester	Oxymetazoline	Ranitidine
Apomorphine	(-) y-Ephedrine	Papaverine	Salicylic acid
Aspartame	Erythromycin	Penicillin-G	Salicylazine
Atropine	β-Estradiol	Perphenazine	Secobarbital
Benzilic acid	Estrone-3-sulfate	Phenelzine	Serotonin
Benzic acid	Ethyl-p-aminobenzoate	Phenobarbital	(5-Hydroxytryptamine)
Benzoylcegonine	Fenoprofen	Phentermine	Sulfamethazine
Benzphetamine	Furosemide	L-Phenylephrine	Sulindac
Bilirubin	Gentisic acid	β-Phenylethylamine	Temazepam
(±) - Brompheniramine	Hemoglobin	Phenylpropanolamine	Tetracycline
Caffeine	Hydralazine		Tetrahydrocortisone
Cannabidiol	Hydrochlorothiazide		3-Acacetate
Cannabinol	Hydrocodone		Tetrahydrocortisone
Chloralhydrate	Hydrocortisone		3-(β-D glucuronide)
Chloramphenicol	O-Hydroxyhippuric acid		Tetrahydrozoline
Chlordiazepoxide	p-Hydroxy-		Thiamine
Chlorothiazide	Methamphetamine		Thioridazine
(±) Chlorpheniramine	3-Hydroxytryptamine		D, L-Tyrosine
Chlorpromazine	Ibuprofen		Tolbutamide
Cholesterol	Imipramine		Triamterene
Clonidine	Iproniazid		Trifluperazine
Cocaine hydrochloride	(±) - Isoproterenol		Trimethoprim
Cocaine	Isoxsuprine		Trimipramine
Cortisone	Ketamine		Tryptamine
(-) Cotinine	Ketoprofen		D, L-Tryptophan
	Labetalol		Tyramine
	Loperamide		Uric acid
	Maprotiline		Verapamil
			Zomepirac

BIBLIOGRAPHY

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

Index of Symbols			
	Storage Temperature		Manufacturer
	Do not reuse		Authorized Representative
	LOT		IVD
	Expiration		Caution, see instructions
	REF		Catalog No.

BIOMERICA, Inc.
1533 Monrovia Ave.
Newport Beach, CA 92663 USA

CE according to IVDD 98/79/EC
MDSS
Buckhardtstr. 1
30163 Hannover, Germany