Phencyclinide (PCP) Test

INTENDED USE
The one-step PCP test is an immunochromatography based one step in vitro test. It is designed for qualitative determination of PCP in human urine specimens. The presence of PCP in human urine as low as 25 ng/ml can be detected.
Always justify preliminary positive and negative results with compelling clinical evidence and professional judgment.

INTRODUCTION
Phencyclidine, commonly known as PCP, is a hallucinogen, which interacts with dopamine, cholinergic and adrenergic systems. It has does dependent stimulant, depressant, hallucinogenic and psychological effects. PCP is mostly administered by oral or intravenously. Even moderate amount of PCP, from 5 to 100 ng/ml, can result in psychotic, violent and self-destruction. At high does, from 100 to 500 ng/ml, PCP can cause convulsions, hypertension, prolonged coma, absent peripheral sensation, and even death. PCP is metabolized via hydroxylation, oxidation, and conjugation with glucuronic acid in the liver. About 10% of the does are excreted in urine as unchanged drug. PCP can be detected in the urine for 7 to 8 days after drug administration. For chronic users, PCP may persist in urine for 2 to 4 weeks.

PRINCIPLE OF THE TEST
The one-step PCP test is based on the principle of specific immunochemical reaction between antibodies and antigens to analyze particular compounds in human urine specimen. The assay relies on the competition for binding antibody between drug conjugate and free drug, which may be present in the urine specimen being tested. When drug is present in the urine specimen, it competes with drug conjugate for the limited amount of antibody-dye conjugate. When the amount of drug is equal or more than the cut-off, 25 ng/ml, it will prevent the binding of drug conjugate to the antibody. Therefore, a positive urine specimen will not show a colored band on the test line zone, indicating a positive result, while the presence of a colored band indicates a negative result.
A control line is present in the test window to work as procedural control. This colored band should always appear on the control line zone if the test device is stored in good condition and the test is performed appropriately.

REAGENTS AND MATERIALS PROVIDED
1. Test device
2. Dropper

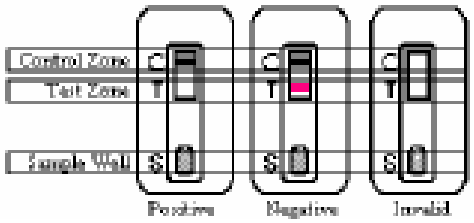
MATERIALS REQUIRED, BUT NOT PROVIDED
1. Clock or timer.
2. Sample collection and testing container.

WARNINGS AND PRECAUTIONS
1. For *in vitro* diagnostic and forensic use only.
2. Do not use the product beyond the expiration date.
3. Handle all specimens as potentially infectious.
4. Do not open foil pouch until it is ready to be tested.
5. Use a new urine specimen cup for each sample to avoid cross contamination.

STORAGE
Store test kit at room temperature (15 - 28°C); do not freeze. Refer to the expiration date for stability.

SAMPLE COLLECTION AND PREPARATION
It is required that approximately 150 µl of sample for each test. Fresh urine specimens do not need any special handling or treatment. Specimens should be collected in a clean, dry, plastic or glass container. It the assay is not performed immediately, urine specimen may be refrigerated at 2-8oC up to 7 days or frozen. Specimens should be brought to room temperature before testing. Urine specimens exhibiting a large amount of precipitate or turbidity should be centrifuged or allowed to settle before testing.

ASSAY PROCEDURE
1. Bring the test components and urine sample to room temperature (15 - 28°C) before testing.
2. Do not break the seal on the foil pouch until ready to perform the test.
3. Open the foil pouches from the notch and removes the test device and dropper. Place the test device on a clean, level surface.
4. Holding the dropper vertically and dispense two to three (2 – 3) full drops of urine without air bubbles into the sample well “S” of the test device.
5. Read the test result at five minutes.
IMPORTANT: The result must be interpreted at five minutes. Waiting more than five minutes may cause the reading to be inaccurate. To avoid confusion, discard the test device after interpreting the result.

INTERPRETATION OF RESULTS


1. **Negative**. Within five minutes two horizontal rose-pink color bands appear indicating the test is negative and the amphetamine level is below the detection sensitivity of 25 ng/ml.
2. **Positive**. At five minutes only one rose-pink color band is visible indicating the test is positive and the amphetamine level is at or above the detection sensitivity of 25 ng/ml.
3. **Invalid**. If at five minutes time no lines appear, or a test line appears without a control line, disregard the results.
An internal procedure control has been incorporated into the test to ensure proper kit performance and reliability.
Note:
1. A very faint colored band in test line zone indicates that the amount of PCP metabolites in the sample is near the cut-off level. These specimens and any positive samples should be confirmed by and alternate method such as GC/MS.
2. The use of an external control is recommended to verify proper kit performance. Quality control samples should be tested according to quality control requirements established

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by the testing laboratory.

LIMITATIONS

1. This product is designed for use with human urine only.
2. Although the test is very accurate, there is a possibility false results will occur due to the presence of interfering substances in the urine.
3. The test is a qualitative screening assay and is not for determining quantitative concentration levels or the level of intoxication.
4. Adulterants such as bleach or other strong oxidizing agents, when added to urine specimens may produce erroneous test results regardless of the analysis method used. If adulteration is suspected, obtain another urine specimen and retest.

PERFORMANCE CHARACTERISTICS

1. **Sensitivity**: The following table lists compounds that are detected by Rapid PCP Tests.

Compounds	Cut-off (ng/ml)	Cross Reactivity (%)
PCP	25	100

2. **Interference testing:** The following substances did not interfere with one-step PCP test.

Glucose 2000 mg/dl	Human albumin 2000 mg/dl
Human hemoglobin 10 mg/dl	Urea 4000 mg/dl
Uric acid 10 mg/dl	

3. **Specificity**: The following compounds show no crossreactivity at concentration up to 100 µg/ml unless specified.

Acetaminophen	4-Acetamidophenol	Acetylsalicylic acid
Amikacin	d,l-Amphetamine	Amitriptyline
Amobarbital	Arterenol	Aspartame
Ascorbic acid	Atrophine	Benzoic acid
Benzoylecgonine	Butabarbital	Caffeine
Camphor	Chloroquine	Chlopheniramine
Cocaine	Cortisone	Deoxyephedrine
Dextromethorphan	Diazepam	Digitoxin
Digoxin	Diphenhydramine	Ecgonine
Ecgonine methyl ester		Ephedrine
Epinephrine	Gentisic acid	Guaiacol glycer-
ester Histamine		
Hydrochlorothiazide	Homatrophine	Imipramine
Ibuprofen	Isoproterenol	Ketamine
Lidocaine	Methamphetamine	3,4±MDA
3,4±MDMA	Meperidine	Methadone
Methaqualone	Methylphenidate	Morphine
Neomycin	Niacinamide	Oxazepam
Perphenazine	Penicillin	G
Phenobarbital	Phenylethylamine-á	
Phenylpropanolamine		Promethazine
Pseudoephedrine	Quinine	Rantidine
Salicyclic acid	Secobarbital	
Tetracycline		
11-nor-.8-THC-9-COOH(10 µg/ml)		
11-nor-.9-THC-9-COOH(10 µg/ml)		
Tetrahydrozoline	Theophyline	
Thioridazine	Trifluoperazine	Tryptophan
Tyramine		

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