



## Acro Rapid Phencyclidine (PCP) Urine Test

Ref No. 1518

### INTENDED USE

The Acro Rapid Phencyclidine Urine Test is a lateral flow, rapid immunoassay for the qualitative detection of phencyclidine in human urine at a cut-off concentration of 25 ng/mL. This test is used to obtain a visual qualitative result and is intended for central laboratory use only.

This assay provides only a preliminary result. Clinical consideration and professional judgment must be applied to a drug test result, particularly in evaluating a preliminary positive result. In order to obtain a confirmed analytical result, a more specific alternate chemical method is needed. Gas Chromatography/Mass Spectroscopy (GC/MS) is the preferred.

### SUMMARY AND EXPLANATION

Phencyclidine, also known as PCP or Angel Dust, 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 powders, and tablet form. The powder is either snorted or smoked after mixing it with marijuana or vegetable matter. Phencyclidine 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 experience mood swings from euphoria to depression. Self-injurious behaviour is one of the devastating effects of Phencyclidine.

The length of time following drug use for which a positive result may occur is dependent upon several factors, including the frequency and amount of drug, metabolic rate, excretion rate, drug half-life, the drug user's age, weight, activity and diet.

### PRINCIPLE OF THE TEST

The Acro Rapid Phencyclidine Urine Test is based on the principle of competitive immunochemical reaction between a chemically labeled drug (drug-protein conjugate) and the drug or drug metabolites, which may be present in the urine sample for the limited antibody binding sites. The test contains a nitrocellulose membrane strip pre-coated with drug-protein conjugate in the test region and a wicking pad containing colored antibody-colloidal gold conjugate. During the test, the urine sample is allowed to migrate upward and hydrate the antibody-colloidal gold conjugate. The mixture then migrates along the membrane chromatographically by capillary action to the immobilized drug-protein band in the test region. When drug is absent in the urine, the colored antibody-colloidal gold conjugate and immobilized drug-protein bind specifically to form a visible line in the test region (test line). When phencyclidine is present in the urine sample, it will compete with the drug-protein conjugate for the limited antibody binding sites. The test line will be less intense with increasing drug concentration. When the drug is present in sufficient concentration in the urine sample, it will fill the limited antibody binding sites, which will inhibit attachment of the colored antibody-colloidal gold conjugate to the drug-protein conjugate in the test region. Therefore the presence of the test line indicates a **negative** result for phencyclidine and the absence of the test line indicates a **preliminary positive** result for phencyclidine.

Another visible line, control line, generated by a different antigen/antibody reaction is also present at a control region (C) next to the test strip. The control line should always appear, regardless of the presence of the drug or drug metabolites in the urine sample. This means that a **negative** urine sample will produce **two** lines (test line and control line), and a **positive** urine sample will generate only **one** line (control line). The presence of control line serves as a built-in control, which demonstrates that the test is performed properly.

### REAGENTS AND MATERIALS PROVIDED

1. Test Cassette contains membrane-immobilized reagents in a protein matrix containing sodium azide as a preservative.
2. Anti-phencyclidine monoclonal antibody is from murine ascites.
2. Dropper. A transfer pipette is included with each test device inside the foil pouch.
3. Test Instructions

### MATERIALS REQUIRED, BUT NOT PROVIDED

1. Timer
2. Sample container

### WARNINGS AND PRECAUTIONS

1. For laboratory *in vitro* diagnostic use only
2. Urine specimens may be potentially infectious. Proper handling and disposal procedures should be established.
3. Avoid cross-contamination of urine samples. Use a new dropper or transfer pipette for adding each test sample.
4. Test device should remain sealed until ready for use.
5. Do not use the test kit after the expiration date.

### STORAGE AND STABILITY

Store at 2-30°C (36-86°F) in the original sealed pouch. Do not freeze.

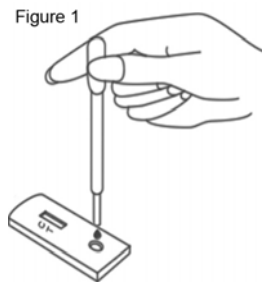
### SPECIMEN COLLECTION AND HANDLING

Fresh urine does not require any special handling or pretreatment. A fresh urine sample should be collected in the container provided. Alternatively, a clean dry plastic or glass container may be used for specimen collection. If the specimen is not immediately tested after the specimen collection, the specimen may be refrigerated at 2-8°C for up to 2 days or frozen at -20°C for longer period of time. Specimens that have been refrigerated must be equilibrated to room temperature prior to testing. Frozen specimens must be thawed and mixed thoroughly prior to testing.

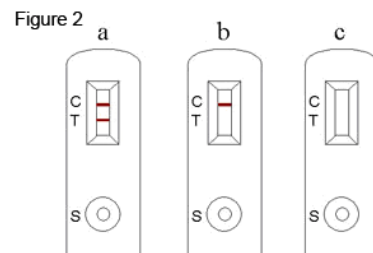
Note: Urine specimens and all materials coming in contact with the specimens should be handled and disposed as if capable of transmitting infection. Avoid contact with skin by wearing gloves and proper laboratory attire.

### ASSAY PROCEDURE

1. Bring the test components and urine sample to room temperature (15° - 28° C) before testing. Do not open the foil pouch until ready to begin testing.
2. Open the foil pouch at the notch and remove the test device and dropper prior to testing. Place the device on a clean, level surface.
3. Hold the dropper vertically and dispense 2 drops (~ 80 µl) of urine sample without air bubbles into the sample well "S" of the test device.
4. Read the result at 5 minutes.



### INTERPRETATION OF RESULTS



1. **Preliminary Positive:** a **rose-pink** color band appears in the Control Zone "C" but not in the Test Zone "T". A preliminary positive result

indicates phencyclidine level in the urine sample is at or above the detection sensitivity of 25 ng/mL. The sample should be confirmed

2. **Negative:** two horizontal *rose-pink* color bands appear, one in the Control zone "C" and one in the Test Zone "T". A negative result indicates phencyclidine level in the urine sample is below the detection sensitivity of 25 ng/mL.

3. **Invalid:** no *rose-pink* bands appear, or a band appears in the Test Zone "T", but not in the Control Zone "C". An invalid result may be due to improper testing procedures or deterioration of the kit components.

**Note:** *There is no meaning attributed to line color intensity or width.*

## QUALITY CONTROL

An internal procedure control is included in the test device. A control line must form regardless of the presence or absence of drugs or metabolites. The presence of the line in the Control region indicates that a proper sample volume has been used. If the line in the Control region does not form, the test is considered invalid.

To ensure proper kit performance, it is recommended that the test devices be tested once a week or prior to use with external controls. External controls are available from commercial sources. It is important to make sure that the control values are within established limits. If the values of external controls do not fall within established limits, the test results are invalid. Additional controls may be tested according to guidelines or requirement of local state, and/or federal regulations or accrediting organizations.

## LIMITATIONS OF PROCEDURE

1. The assay is designed for use with human urine only.
2. A preliminary positive result indicates only the presence of phencyclidine and does not indicate or measure intoxication
3. There is a possibility that technical or procedural error as well as other substances as factors not listed may interfere with the test and cause false results. See SPECIFICITY section for substances that will produce positive results, or that do not interfere with the test performance.
4. If adulteration is suspected, the test should be repeated with a new sample.
5. Certain over the counter or prescription medications (or certain foods) may cause false results

## PERFORMANCE CHARACTERISTICS

1. **Sensitivity.** The Acro Rapid Phencyclidine Urine Test detects phencyclidine and its metabolites in urine at concentrations equal to or greater than 25 ng/mL.
2. **Specificity.** Interference of substances that may be present in urine specimens, as well as effect of sample pH and specific gravity was also studied.
  - a. Cross-reactivity of non-phencyclidine related compounds at concentrations much higher than normally found in the urine of people using or abusing them were tested using the assay devices. No cross-reactivity was detected with the substances listed in Table I.
  - b. Table II lists phencyclidine related substances and concentrations that produced results approximately equivalent to the cutoff level for phencyclidine.
  - c. Varying sample pH within the range of 4 and 9 has no significant effect on the assay results.
  - d. Varying sample specific gravity within the range of 1.003 and 1.040 has no significant effect on the assay results.

**Table-I: Compounds tested and found not to cross-react with the test at the concentrations of 10 µg/mL and 100 µg/mL in urine.**

Acetaminophen	Hemoglobin
Acetone	Ibuprofen
Albumin	(+/-)-Isoproterenol
Ampicillin	Ketamine
Ascorbic Acid	Levorphanol
Aspartame	Lidocaine
Aspirin	(+)-Naproxen
Atropine	Niacinamide
Benzocaine	Nicotine
Bilirubin	(+/-)-Norephedrine
Caffeine	Oxalic Acid
Chloroquine	Penicillin-G

(+)-Chlorpheniramine	Pheniramine
(+/-)-Chlorpheniramine	Phenothiazine
Creatine	1-Phenylephrine
Dexbrompheniramine	β-Phenylethylamine
Dextromethorphan	Procaine
Diphenhydramine	Quinidine
Dopamine	Ranitidine
(+/-)-Epinephrine	Riboflavin
Erythromycin	Sodium Chloride
Ethanol	Sulindac
Furosemide	Theophylline
Glucose	Tyramine
Guaiacol Glyceryl Ether	4-Dimethylaminoantipyrine
	(1R, 2S)-(-)-N-Methyl-Ephedrine

**Table-II: Concentration of phencyclidine-related compounds showing a positive response approximately equivalent to the phencyclidine cut-off set for the test.**

Compound /	Concentration in ng/ml
Phencyclidine	25
Phencyclidine Morpholine	12.5
4-Hydroxyphencyclidine	12,500

3. **Accuracy.** The accuracy study was performed by testing clinical phencyclidine urine samples with the device and comparing the results with GC/MS analysis results.

Acro Phencyclidine	GC/MS				Percent Agreement with GC/MS
	Negative, <50% cutoff	Near Cutoff Negative (between -50% and cutoff)	Near Cutoff Positive (between cutoff and +50%)	Positive (>+50% Cutoff)	
Positive	0	4	6	37	43/47 = 91%
Negative	70	8	5	0	78/83 = 94%

4. **Reproducibility/Cut-off study.** The reproducibility of the assay at the cut-off and other concentrations was determined by the repetitive assaying of seven levels of phencyclidine controls. The resultant data are summarized as follows:

Phencyclidine conc.	# Tested	# Positive (+)	# Negative (-)
0 ng/mL	60	0	60
12.5 ng/mL	60	0	60
18.75 ng/mL	60	13	47
25 ng/mL	60	34	26
31.25 ng/mL	60	45	15
37.5 ng/mL	60	60	0
50 ng/mL	60	60	0

## BIBLIOGRAPHY

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