PARAMCARE LIFE SCIENCES PVT. LTD.
where innovation starts...

PARAMCARE™

PCP Rapid Test Kit

The PCP Rapid Test kit is a rapid chromatographic immunoassay for the qualitative detection of Phencyclidine in human Urine specimens.

For *In-Vitro Diagnostic* Use only

ORDER INFORMATION

Pack Size	REF
01 Test	PPCP 01
05 Tests	PPCP 05
10 Tests	PPCP 10
25 Tests	PPCP 25
50 Tests	PPCP 50

CLINICAL SIGNIFICANCE

Phencyclidine is central nervous system (CNS) depressants. 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. Phencyclidine 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 Phencyclidine. Phencyclidine is excreted in the urine as unchanged drug (4% to 19%) and conjugated metabolites (25% to 30%) with a half-life of about 12 hours.

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.

KIT COMPONENTS

• Test Cassettes • Droppers • Package Insert

MATERIALS REQUIRED BUT NOT PROVIDED

• Specimen Collection Containers • Timer

PRECAUTIONS

1. For professional *in vitro* diagnostic use only. Do not use after the expiration date.
2. Wear protective gloves while handling specimens wash thoroughly afterwards.
3. The device is sensitive to humidity as well as heat. Therefore, take out the device from seal pouch before test.
4. Do not mix reagents from different lot.
5. Dispose all the samples and kits properly as per the instruction after test in accordance in GLP.
6. Follow the testing procedure exactly as mention in the insert.

STORAGE AND STABILITY

1. The kit can be stored at room temperature or refrigerated (2-30°C). The test device must remain in the sealed pouch until use. DO NOT FREEZE.
2. Do not use beyond the expiration date.
3. Do not use the test kit, if the pouch is damaged or seal is broken.

SPECIMEN COLLECTION & PREPARATION

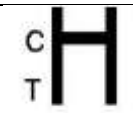
- PCP Rapid Test kit is intended for use with human urine specimens only.
- Urine collected at any time of the day may be used.
- Urine specimens must be collected in clean, dry containers.
- Perform testing immediately after specimen collection.
- Do not leave specimens at room temperature for prolonged periods. Urine specimens may be stored at 2-8°C for up to 2 days. For long term storage, specimens should be kept below -20°C.
- Bring specimens to room temperature prior to testing. Frozen specimens must be completely thawed and mixed well prior to testing. Avoid repeated freezing and thawing of specimens.

DIRECTIONS FOR USE

Allow the test device and specimen to equilibrate at room temperature (15-30°C) before testing.

1. Bring the pouch to room temperature before opening it. Remove the test cassette from the sealed pouch and use it within 20 minutes.
2. Place the cassette on a clean and level surface.
3. Check the colour of the desiccant pouch. It should be blue. If the desiccant has turned colourless or pink, discard the test device and use another device. Once opened, the device must be used immediately.
4. Label the device with patient identity and place the testing device on a flat horizontal surface.
5. Dispense 2 drops urine sample into the each sample well (S) of the device using sample dropper. Avoid trapping air bubbles in the sample well, while dispensing the sample. Alternatively, carefully dispense 50 µl urine in each sample well using pipette.
6. Wait for the colored line(s) to appear. Read results after 5 minutes. **Note**: Do not interpret the result after 10 minutes.

INTERPRETATION OF RESULTS

Positive Result	
Negative Result	

1) Positive
The control line is the only visible line on the test device. This is indicative of presence of PCP above 25 ng/ml

2) Negative
The control line and Test line is visible line on the test device. This no Detected PCP below 25 ng/ml.

3) Invalid

The control line fails to appear. Insufficient specimen volume or incorrect procedural techniques are the likeliest reasons for control line failure. Repeat the test using a new test device.

Quality Control

Internal procedural controls are included in the test individually. A colored line appearing in control line region (C) is the internal procedural control. It confirms sufficient specimen volume and correct procedural technique. Control standards are not supplied with this kit; however, it is recommended that positive and negative controls be tested as a good laboratory practice to confirm the test procedure and to verify proper test performance.

Limitations of the Test

1. The PCP Rapid Test (Urine) is for in vitro diagnostic use only. This test should be used for detection of Phencyclidine in human urine at the cut off of 25 ng/ml. Neither the quantitative value nor the rate of increase in the concentration of Phencyclidine can be determined by this qualitative test.
2. A negative result can occur if the level of Phencyclidine present in the specimen is below the cut off value (25 ng/ml) present during the stage which a sample is collected. However, a negative test result does not preclude the possibility of PCP presence.
3. Human urine Samples suspecting PCP should be confirmed by other methods such as Gas chromatography/mass spectrometry.
4. As with all diagnostic tests, all results must be considered with other clinical information available to the physician

Detection Limitation

The PCP Rapid Test can detect PCP above as 25 ng/ml.

Sensitivity and Specificity

A total of 140 normal human urine specimens were collected from human subjects and 3 positive control samples tested by PCP Rapid Test Kit. These specimens were confirmed by commercially available kit. Comparison for all subjects is showed in the following table.

Commercial PCP Rapid Test Results	PCP Rapid Test		Total
	Positive	Negative	
Positive	3	0	3
Negative	2	138	140
Total	5	138	143

Relative Sensitivity: 100%, Relative Specificity: 98.57%, Overall Agreement: 98.60%

Specificity and cross-reactivity

The following substances were tested and confirmed did not interfere with by PCP Rapid Test Kit at the listed concentrations.

Substances	Concentration
Glucose	2000 mg/dl
Human Albumin	2000 mg/dl
Human hemoglobin	10 mg/dl
Urea	4000 mg/dl
Uric acid	10 mg/d

Drugs derivative	Concentration (ng/ml)
Morphine	2,000
Codeine	2,000
Ethylmorphine	5,000
Hydrocodone	12,500

BIBLIOGRAPHY

1. Baselt RC. Disposition of Toxic Drugs and Chemicals in Man. 2nd ed. Davis: Biomedical Publications; 1982.
2. 2. Hawks RL, Chiang CN, eds. Urine Testing for Drugs of Abuse. Rockville: Department of Health and Human Services, National Institute on Drug Abuse; 1986.
3. 3. Substance Abuse and Mental Health Services Administration. Mandatory Guidelines for Federal Workplace Drug Testing Programs. 53

GLOSSARY OF SYMBOL

	Consult Instruction for Use
	Catalog Number
	Store between
	Manufacturer
	Keep away from sunlight

Paramcare Life Sciences Private Limited, G/F-12/13, Evershine-2, Survey No. 307/3/1, Balitha N.H No 48, Vapi, Valsad, Gujarat, 396191.
Email: contact@paramcarelifesciences.com
Website: www.paramcarelifesciences.com