

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 test will detect other related compounds, please refer to the Analytical Specificity table in this package insert.

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, 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 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. 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.

KIT COMPONENTS

Individually packed test strips	Each Device contains colored conjugates and reactive reagents pre-spread at the corresponding regions.
Package insert	For operation instruction.

MATERIALS REQUIRED BUT NOT PROVIDED

Specimen collection container	For specimens collection use.
Timer	For timing use.

PRECAUTIONS

- For professional *in vitro* diagnostic use only.
- Do not use after expiration date indicated on the package. Do not use the test if its foil pouch is damaged. Do not reuse tests.
- This kit contains products of animal origin. Certified knowledge of the origin and/or sanitary state of the animals does not totally guarantee the absence of transmissible pathogenic agents. It is therefore, recommended that these products be treated as potentially infectious, and handled observing the usual safety precautions (do not ingest or inhale).
- Avoid cross-contamination of specimens by using a new specimen collection container for each specimen obtained.

- Read the entire procedure carefully prior to performing any tests.
- Do not eat, drink or smoke in the area where the specimens and kits are handled. Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout the procedure and follow the standard procedures for proper disposal of specimens. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed.
- Humidity and temperature can adversely affect results.
- The used testing materials should be discarded in accordance with local, state and/or federal regulations.

STORAGE AND STABILITY

- The kit should be stored at 2-30°C until the expiry date printed on the sealed pouch.
- The test must remain in the sealed pouch until use.
- Do not freeze.**
- Cares should be taken to protect components in this kit from contamination. Do not use if there is evidence of microbial contamination or precipitates. Biological contamination of dispensing equipments, containers or reagents can lead to false results.

SPECIMEN COLLECTION AND STORAGE

- The PCP One Step Phencyclidine Test Device(Urine) is intended only for use with human urine specimens.
- Collected urine specimens must be put in clear and dry containers. Ensure that a sufficient quantity of the specimen is collected to allow submerging the dipping area of the strip.
- Perform the testing immediately after the specimen collection. Do not leave the specimens at room temperature for prolonged periods. Specimens may be stored at 2-8°C for up to 48 hours. 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.
- Pack the specimens in compliance with applicable regulations for transportation of etiological agents, in case they need to be shipped.

PROCEDURE

Bring tests, specimens and/or controls to room temperature (15-30°C) before use.

- Remove the test from its sealed pouch and use it as soon as possible. To obtain a best result, the assay should be performed within one hour.
- Hold the Device at the handle with the product name imprints. Do not touch the membrane part of the Device to avoid contamination.
- Dip the test Device vertically in the urine specimen for at least 10-15 seconds.** Do not pass the maximum line (MAX) on the test Device when immersing the strip. As the test begins to work, you will see color move across the membrane.
- Take the Device out of the specimen afterwards and place it on a non-absorbent flat surface. Start the timer and wait for the colored line(s) to appear.
- The result should be **read at 5 minutes**. Do not interpret the result after 10 minutes.

INTERPRETATION OF RESULTS

POSITIVE RESULT:



Only one colored band appears in the control region (C). No apparent colored band appears in the test region (T).

NEGATIVE RESULT:



Two colored bands appear on the membrane. One band appears in the control region (C) and another band appears in the test region (T).

INVALID RESULT:



Control band fails to appear. Results from a test which has not produced a control band at the specified reading time must be discarded. Please review the procedure and repeat with a new test. If the problem persists, discontinue using the kit immediately and contact your local distributor.

NOTE:

- The intensity of the color in test region (T) may vary depending on the concentration of aimed substances present in the specimen. Therefore, any shade of color in the test region should be considered negative. Besides, the concentration level can not be determined by this qualitative test.
- Insufficient specimen volume, incorrect operation procedure, or performing expired tests are the most likely reasons for control band failure.

LIMITATIONS OF THE TEST

- 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}
- 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










A. Accuracy

The accuracy of the PCP One Step Phencyclidine Test Device(Urine) was compared and checked against commercially available tests with a threshold value at the same cut-off levels. Urine samples taken from volunteers claiming to be non-users were examined under both tests. The results were >99.9% in agreement.

B. Reproducibility

The reproducibility of the PCP One Step Phencyclidine Test Device(Urine) was verified by blind tests performed at four different locations. Samples with Phencyclidine concentrations at 50% of the cut-off were all determined to be negative, while samples with Phencyclidine concentrations at 200% of the cut-off were all determined to be positive.

Index or Symbols

 Attention, see instructions for use	 Tests per Kit	 Manufacturer
 For <i>in vitro</i>	 Use by	 Do not reuse
 Store between 2-30°C	 Lot Number	 Catalogue Number

