PCP Phencyclidine strip CE

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For professional *in vitro* diagnostic use only			

PCP Phencyclidine

A rapid test for the qualitative detection of Phencyclidine (PCP) in human urine.
ONE STEP

PRINCIPLE

LINEAR PCP Phencyclidine strip 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.

REAGENT COMPOSITION

The LINEAR PCP Phencyclidine strip contains mouse monoclonal anti-Phencyclidine-coupled particles and Phencyclidine-protein conjugate. A goat antibody is employed in the control line system.

PACKAGING CONTENTS

REF 4452150 50 PCP Phencyclidine test strip.

STORAGE AND STABILITY

Store at 2-30ºC.
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

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.
Urine specimens may be stored at 2-8°C for up to 48 hours prior to testing. For long-term storage, specimens may be frozen and stored below -20°C. Frozen specimens should be thawed and mixed before testing.

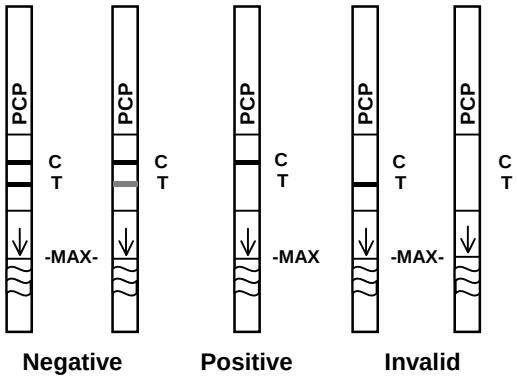
MATERIAL REQUIRED

- Timer.
- Specimen collection container .

PROCEDURE

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

1. Bring the pouch to room temperature before opening it. Remove the test strip from the sealed pouch and use it as soon as possible.
2. 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.
3. Place the test strip on a non-absorbent flat surface, start the timer and wait for the red line(s) to appear. The result should be **read at 5 minutes**. Do not interpret the result after 15 minutes.



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. 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.

CLINICAL SIGNIFICANCE

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. Phencyclidine is excreted in the urine as unchanged drug (4% to 19%) and conjugated metabolites (25% to 30%).[1] Test to monitor therapeutic measures related to the study and control of detoxification treatments of drug of abuse and its effects in laboratory tests.

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ANALYTICAL PERFORMANCE

A. Accuracy

The accuracy of the LINEAR PCP Phencyclidine strip was compared and checked against a commercially available test with a threshold value of 25 ng/mL. 120 urine samples taken from volunteer test persons who claim to be non-consumers was examined under both tests. The results were 100% in agreement.

B. Reproducibility

The reproducibility of the LINEAR PCP Phencyclidine strip was verified by blind tests performed at a four different locations. All 60 utilized samples with a PCP-concentration of 6,25 ng/mL yielded a negative result. All 60 samples with a PCP-concentration of 75 ng/mL yielded a positive result. No significant differences were observed between test results of the different evaluation sites.

C. Precision

Test precision was determined by blind tests with control solutions. Controls with a PCP-concentration of 6,25 ng/mL yield a negative result. Controls with a PCP-concentration of 75 ng/mL provide a positive result.

D. Specificity

The specificity of the LINEAR PCP Phencyclidine strip was tested with the substances listed below, all of which can be found in a normal urine specimen. These substances was added to normal drug free urine.

The following compounds with a similar chemical structure yielded a positive result at the specified concentration:

COMPOUND	CONCENTRATION (ng/mL)
Phencyclidine	25
Thienylcyclohexylpiperidine (TCP)	3,000

All following listed compounds reacted negative up to a concentration of 100 µg/mL.

Acetaminophen	Hydromorphone
Acetone	Imipramine
Albumin	(+/-)-Isoproterenol
Amitriptyline	Lidocaine
D-Amphetamine	Meperidine
L-Amphetamine	Methamphetamine
Ampicillin	Methaqualone
Aspartame	(1R 2S)-(-)-N-Methyl-Ephedrine
Aspirin	Methylphenidate
Atropine	Morphine
Benzocaine	Naloxone
Benzoylecgonine	Naltrexone
Bilirubin	(+)-Naproxen
(+)-Brompheniramine	(+/-)-Norephedrine
Caffeine	Oxalic Acid
Chloroquine	Oxazepam
(+/-)-Chlorpheniramine	Oxycodone
(+)-Chlorpheniramine	Penicillin-G
Chlorpromazine	Pentermine
Cocaine	Pentobarbital
Creatine	Pheniramine
(-)-Deoxyephedrine	Phenobarbital
Dextromethorphan	Phenothiazine
4-Dimethylaminoantipyrine	L-Phenylephrine
Dopamine	β-Phenylethylamine
Doxylamine	Procaine
Ecgonine	D-Propoxyphene
Ecgonine Methyl Esther	Quinidine
(+/-)-Ephedrine	Ranitidine
(-)-Ephedrine	Secobarbital
(+)-Epinephrine	Sodium Chloride
Erytromycin	Sulindac
Ethanol	Thioridazine
Furosemide	11-nor-Δ^9-THC-9-carboxylic acid
Glucose	Trifluorperazine
Guajacol Glyceryl Ether	Trimethobenzamide
Hemoglobin	Tyramine
Hydrocodone	Vitamin C

NOTES

1. The LINEAR PCP Phencyclidine strip 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]
2. 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.
3. A positive result indicates presence of the drug or its metabolites but does not indicate level of intoxication, administration route or concentration in urine.
4. 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.
5. Test does not distinguish between drugs of abuse and certain medications.

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