

HEALTH-CHEM DIAGNOSTICS, LLC

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ONE STEP DRUGS OF ABUSE TEST STRIP - PHENCYCLIDINE (PCP)TM

NAME AND INTENDED USE

The Health-Chem **One Step Drugs of Abuse Test Strip - Phencyclidine (PCP)**TM is a rapid, qualitative, competitive binding immunoassay for the determination of Phencyclidine (PCP) and its metabolites in urine in a convenient One Step strip test format. This test is not intended to monitor drug levels, but only to screen urine samples for the presence of Phencyclidine (PCP) and its metabolites. Both the testing and the results of the testing are intended to be used by medical and legal professionals only. The test should not be used without appropriate supervision. The **TCPI One Step Drugs of Abuse Test Strip - Phencyclidine (PCP)**TM assay is not intended for Over The Counter (OTC) sale to lay persons.

The **One Step Drugs of Abuse Test Strip - Phencyclidine (PCP)**TM or provides only preliminary data which should be confirmed by other methods such as gas chromatography/mass spectroscopy (GC/MS). Clinical considerations and professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are indicated. The **One Step Drugs of Abuse Test Strip - Phencyclidine (PCP)**TM is not intended to monitor drug levels, but only to screen urines for the presence of phencyclidine (PCP) and its metabolites.

EXPLANATION OF THE TEST

The method employs unique polyclonal antibodies to selectively identify Phencyclidine (PCP) in test samples with a high degree of sensitivity. Phencyclidine, commonly known as "Angel Dust", is used primarily as a recreational drug for its hallucinogenic affects. It is generally self-administered by intravenous injection or by inhalation and concentrates fastest in fatty tissues and the brain. Excretion patterns vary widely with the individual. Methods historically used for detecting phencyclidine in biological fluids include thin-layer chromatography, gas chromatography, ultraviolet spectroscopy, enzyme immunoassay and radio immunoassay. While confirmation techniques other than GC/MS may be adequate for some drugs, GC/MS is generally accepted as a vigorous confirmation technique for all drugs since it provides the best level of confidence in the result. The legally allowable level for Phencyclidine (PCP) is set at 25 ng/ml of urine by the National Institute on Drug Abuse.

The **One Step Drugs of Abuse Test Strip - Phencyclidine (PCP)**TM test is an easy, fast, visually read competitive binding immunoassay method for the screening of urine for the presence of Phencyclidine (PCP) without the need for instrumentation.

PRINCIPLE OF THE PROCEDURE

The **One Step Drugs of Abuse Test Strip - Phencyclidine (PCP)**TM test consists of a chromatographic absorbent device in which the drug or drug metabolites in the sample compete with a drug conjugate immobilized on a porous membrane support for the limited antibody sites. As the test sample flows up through the absorbent device, the labeled antibody-dye conjugate binds to the free drug in the specimen forming an

antibody-antigen complex. This complex competes with the immobilized antigen conjugate in the positive reaction zone and will not produce a magenta color band when the drug is above the detection level of 25 ng/ml which is suggested for the immunoassay method. Unbound dye conjugate binds to the reagent in the negative control zone, producing a magenta color band, demonstrating that the reagents and device are functioning correctly.

A **NEGATIVE** specimen produces two distinct color bands in both the test line and control area.

A **POSITIVE** specimen produces only one color band in the control area.

MATERIALS REQUIRED BUT NOT PROVIDED

1. Specimen collection containers.
2. Clock or timer.
3. 13 x 100mm Test Tube.

WARNINGS AND PRECAUTIONS

1. For **in vitro** diagnostic use only.
2. For professional medical and legal use only.
3. Avoid cross contamination of urine samples by using a new urine specimen cup for each sample.
4. Do not use the test strip beyond the expiration date imprinted on the outside of the foil pouch.
5. Urine specimens may be infectious. Upon completion of all testing dispose of residual urine in a medically approved manner.
6. Properly handle and dispose of all used reaction devices in an approved biohazard container.

STORAGE AND STABILITY

The reagents supplied can be stored under refrigeration (2° - 8°C)(35° - 46°F) **[DO NOT FREEZE]** or at room temperature (18° - 30°C)(64° - 86°F) and will be stable for 12 months.

SAMPLE COLLECTION AND PREPARATION

Urine (1.0 ml) - The sample must be collected in a clean, dry container, either plastic or glass, without any preservatives. Urine specimens may be refrigerated (2°-8°C) (35°-46°F) and stored up to 48 hours, or frozen (-20°C or colder) (-4°F or colder) prior to assaying. If samples are refrigerated or frozen, they should be allowed to come to room temperature before testing. Urine samples exhibiting visible precipitates should be filtered, centrifuged or allowed to settle so that clear aliquots can be obtained for testing.

ASSAY PROCEDURE

1. Remove **One Step Drugs of Abuse Test Strip - Phencyclidine (PCP)**TM from its protective foil wrapper by tearing along the notch.

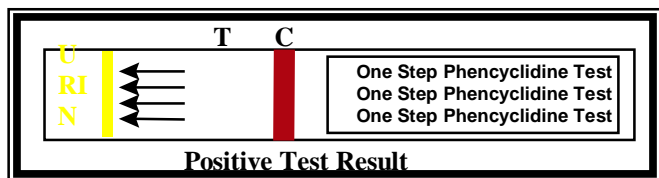
- Add 1 ml of urine to be tested to a 13 x 100mm test tube. Holding the strip in a vertical position, place it into the urine and simultaneously start timing. Make sure that only the end with the arrow pointing down is placed in the urine specimen. The urine level should not be higher than the maximum fill line indicated on the strip.
- Read the results after 3 minutes. Test results should not be interpreted after 5 minutes.

NOTE:

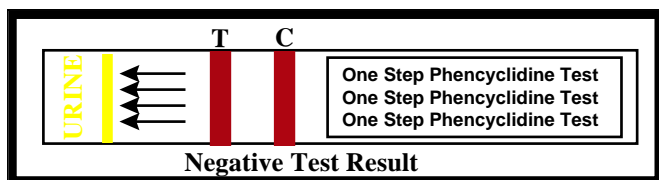
Refrigerated strips should be allowed to come to room temperature before opening the pouch.

READING THE TEST RESULTS

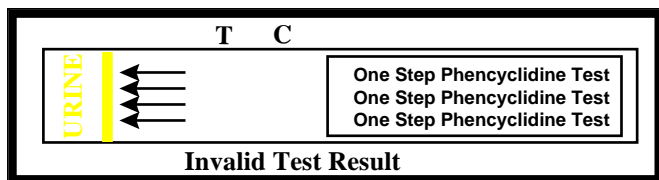
- POSITIVE:** One magenta band appears on the control region. No visible band on the test region (lower portion of the read area). This is an indication that the Phencyclidine (PCP) level is above the detection sensitivity level of 25 ng/ml of urine.



- NEGATIVE:** In addition to the control band, a magenta band also appears on the test region (lower portion of the read area). If this is the case, the Phencyclidine (PCP) level is below the detection sensitivity level of 25 ng/ml of urine.



- INVALID:** If there are no distinct color bands in both the upper and lower portions of the read area, (lower portion of the strip), or no band in the control region (upper portion of the read area), then the test results are invalid. It is recommended that the specimen be retested.



QUALITY CONTROL

Each reaction strip has its own built-in quality control indicator. If after performing the test no line is visible on the strip, the strip may have been placed into the tube incorrectly or the test device may have deteriorated. The assay will have to be repeated using a new TCPI **One Step Drugs of Abuse Test Strip - Phencyclidine (PCP)™**. Re-read the instructions carefully or call HCD's Hotline for assistance (800-482-2907).

Good laboratory practice recommends the use of control material to test each product shipment or whenever it is necessary to validate reagent performance and reliability. Commercial controls from BioRad, Uro-Qual Abutrol, Utak, and Alltech are available for validation of the device functionality. NIDA recommended guidelines for drugs of abuse screening indicate that controls should contain the drug of abuse analyte

at levels at least 20% above the NIDA cut off values.

AFTER TESTING

Urine specimens may be infectious. Properly handle and dispose of all used reaction devices in an approved biohazard container. Residual urine should be disposed of in a medically approved manner after completion of all testing including the confirmatory testing. Sample disposal may be controlled by legal chain of custody considerations.

PERFORMANCE CHARACTERISTICS

The **One Step Drugs of Abuse Test Strip - Phencyclidine (PCP)™** detects phencyclidine (PCP) and its metabolites in urine at concentrations agreed to or greater than 25 ng/ml.

LIMITATIONS OF THE TEST

- This product is designed to be used for the detection of Phencyclidine (PCP) and its metabolites in human urine only.
- Although HCD's **One Step Drugs of Abuse Test Strip - Phencyclidine (PCP)™** test is very accurate in detecting the urine Phencyclidine (PCP) level, there is a possibility of false results due to the presence of interfering substances in the urine.
- The test is a qualitative screening assay and cannot be used to determine the quantitative level of Phencyclidine (PCP) in urine.
- 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.

BIBLIOGRAPHY

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Manufactured in the USA by:
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