


**ADVANCED QUALITY™ ONE STEP Phencyclidine(PCP) TEST**
**(Urine)**FOR *IN VITRO* DIAGNOSTIC USE ONLY**INTENDED USE**

THE ADVANCED QUALITY™ ONE STEP PHENCYCLIDINE (PCP) TEST IS A RAPID, IMMUNOCHROMATOGRAPHIC ASSAY FOR THE DETECTION OF PCP IN HUMAN URINE. THE TEST IS USED TO SCREEN URINE FOR THE PRESENCE OF PCP AT A CUTOFF CONCENTRATION OF 25NG/ML. THE TEST IS INTENDED FOR USE BY HEALTHCARE PROFESSIONALS ONLY.

*This test provides only a preliminary analytical test result. A more specific alternative chemical method must be used in order to obtain a confirmed analytical result. Gas chromatography/mass spectrophotometry (GC/MS) is the preferred confirmatory method. Clinical considerations and professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are indicated.*

**SUMMARY AND EXPLANATION OF THE TEST**

PCP is a hallucinogen which has stimulant, depressant, hallucinogenic, and analgesic properties. PCP is administered by oral or nasal ingestion, smoking, or intravenous injection. Even moderate amounts of PCP, from 5 to 100 ng/ml, can result in psychotic, violent and self-destruction. At high dose, from 100 to 500 ng/ml or higher, PCP can cause convulsions, hypertension, prolonged coma, absent peripheral sensations, and even death.

PCP is metabolized via hydroxylation, oxidation, and conjugation with glucuronic acid in the liver. A relatively small portion ( 4 to 19 % ) of the original does is excreted unchanged as PCP in the urine. PCP levels in urine are pH-dependent. Excretion of PCP from body is greatly increased by acidification of the urine.

The test is a qualitative, visual screening immunoassay. The method employs unique antibodies to selectively identify the drug in the test urine with a high degree of sensitivity and specificity.

**PRINCIPLE OF THE PROCEDURE**

The test device 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 immobilized antigen conjugate in the positive reaction zone and will not produce a magenta color band when the drug is above the detection level 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 (2) distinct color bands, one in the test area and one in the control region.

A **positive** specimen produces only one (1) color band in the control region.

**REAGENTS AND MATERIALS SUPPLIED**

1. Test strips individually foil pouched with a desiccant
2. Package insert

**MATERIALS REQUIRED BUT NOT PROVIDED**

1. Clock or Timer
2. Positive and negative urine controls available from commercial distributors.

**WARNINGS AND PRECAUTIONS**

1. For *in vitro* diagnostic use only.
2. Avoid cross contamination of urine samples by using a new urine specimen cup for each sample.
3. Do not use the kit beyond the expiration date printed on the outside of the foil pouch.
4. Do not open the foil pouch until urine specimen is collected and ready to be tested.
5. Urine specimens may be infectious. Handle and dispose of all used specimens and devices in an approved biohazard container.

**STORAGE AND STABILITY**

The test device can be stored under refrigeration and at room temperature (2 - 30° C) and will be stable until the expiration date. **Do not** open foil pouch until ready to test.

**SAMPLE COLLECTION AND PREPARATION**

10 ml of urine must be collected in a clean, dry, plastic or glass container, that does not contain preservative. Some plastics may adsorb drugs. If not tested immediately, urine specimens may be stored refrigerated at 2-8°C for up to 7 days and then frozen(-20° C or colder) prior to assaying. Refrigerated or frozen samples must be warmed to room temperature and gently mixed before testing. Urine samples exhibiting visible precipitates or turbidity should be centrifuged or allowed to settle so a clear aliquot may be sampled for this assay. Collection of samples may require mandatory procedures and custody and control records. Poppy seed ingestion has been associated with positive test results in some samples.

**ASSAY PROCEDURES**

1. Bring all materials and specimens to room temperature.
2. Remove test strip from the sealed foil pouch.
3. Dip the test strip into the urine sample with the arrows pointing toward the specimen.
4. The urine level should reach the maximum line marked on the strip, but must not exceed the maximum line.
5. Hold the strip in the urine until a reddish color appears at the lower edge of the test membrane (approximately 10 seconds).
6. Withdraw the strip and place it face up on a clean, dry surface.
7. Read the result between 3 - 8 minutes after adding the sample.

**READING THE TEST RESULTS**

*Read test results between 3 - 8 minutes.*

**Do not interpret results after 8 minutes.**

**NEGATIVE** Two (2) pink/purple bands form. In addition to the control band, a pink/purple band also appears in the test region.

*Note: This immunoassay is a screening test. A negative result indicates the drug level is below the detection sensitivity. It is important to understand that concentrations of the drug below cut off may cause a faint "ghost line" to form in the test region. This "ghost line" should be considered a negative result.*

**POSITIVE** One (1) pink/purple band appears in the control region. No band is found in the test region. This is an indication that the drug level is above the detection sensitivity level.

**INVALID** If there is no pink/purple band in the control area of the strip, the test result is invalid. Retest the sample using a new device.

*Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly when preliminary results are positive. Positive results should be confirmed by an alternate method such as GC/MS.*

**QUALITY CONTROL**

1. Each test device has a control band to indicate that the sample volume and migration is adequate, and that the colloidal gold is dissolving as expected. An invalid result must be repeated using a new test device.
2. Positive and negative, drug free urine controls can be used to validate reagent performance and establish test reliability. Commercial drug urine controls are available, but not provided with this test. NIDA recommended guidelines for drugs of abuse screening indicate controls should contain the drug at a level at least 20% above the NIDA cutoff value. If control values do not fall within the established limits, assay results

#### EXPECTED RESULTS

The Advanced Quality PCP Test identifies PCP in human urine at a cutoff concentration of 25ng/mL. The concentration of the drug can not be determined using this test. The test is intended to screen urine to separate a negative result from a presumptive positive result. All positive results must be confirmed using an confirmatory method, preferably GC/MS.

#### PERFORMANCE CHARACTERISTICS

##### Sensitivity:

The Advanced Quality One Step PCP Test detects PCP in human urine at 25 ng/mL, as suggested for the immunoassay method.

##### Specificity and Interference

Compounds that give positive results:

|               |         |
|---------------|---------|
| Phencyclidine | 25ng/ml |
| Naloxone      | 20µg/ml |

Compounds that give negative results at concentration up to 100 µg/ml (unless noted):

|                         |                                       |
|-------------------------|---------------------------------------|
| 4-acetamidophenol       | ketamine                              |
| acetylsalicylic acid    | lidocaine                             |
| amikacin                | methadone                             |
| amitriptyline           | methamphetamine                       |
| amphetamine             | morphine                              |
| arterenol               | 3,4-methylenedioxymethampheta-mine    |
| aspartame               | neomycin                              |
| benzoylecgonine         | niacinamide                           |
| caffeine                | 11-nor-delta-8-THC-9-COOH (10 µg/ml ) |
| camphor                 | 11-nor-delta-9-THC-9-COOH(10 ug/ml)   |
| chloroquine             | oxazepam                              |
| chlorpheniramine        | perphenazine                          |
| cortisone               | phenobarbital                         |
| deoxyepinephrine        | phenylethylamine-α                    |
| dextromethorphan        | phenylpropanolamine                   |
| digitoxin               | promethazine                          |
| digoxin                 | pseudoephedrine                       |
| epinephrine (±)         | rantidine                             |
| ephedrine               | salicylic acid                        |
| gentisic acid           | secobarbital                          |
| glucose                 | tetracycline                          |
| histamine               | tetrahydrozoline                      |
| guaiacol glyceryl ether | theophylline                          |
| imipramine              | thioridazine                          |
| isoproterenol           | trifluoperazine                       |

#### LIMITATIONS OF THE TEST

1. This product is designed to be used for the detection of PCP in human urine only.
2. Although The Advanced Quality One Step PCP Test is very accurate in detecting the level of PCP in urine, there is a possibility of false results due to the presence of interfering substances in the urine.

3. The test is a qualitative screening assay and is not suggested for determining the quantitative level of PCP in urine.
4. 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.
5. There is the possibility that other substances and/or factors not listed above may interfere with the test and cause false results, e.g. technical or procedural errors.

#### BIBLIOGRAPHY

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3. R.C.Baselt, Disposition of Toxic Drugs and Chemicals in Man, 2nd ed., Biomedical publ., Davis, CA, 1982, p.488.

