

DRG QuickScreen™ One Step Phencyclidine Screening Test (RAP-2833)

Revised 16 Dec. 2003

Intended Use

The QuickScreen™ One Step Phencyclidine Screening Test is a rapid, qualitative immunoassay for the detection of Phencyclidine in urine. The cutoff concentration for this test is 25 ng/mL, as recommended by the Substance Abuse and Mental Health Services Administration (SAMHSA), formerly the U.S. National Institute of Drug Abuse (NIDA).

This test provides only a preliminary test result. A more specific alternate testing method must be used in order to obtain a confirmed analytical result. Gas chromatography/mass spectrometry (GC/MS) is the preferred confirmatory method. Other chemical confirmation methods are available. Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are observed.

Summary & Explanation

Phencyclidine, commonly known as PCP or “angel dust,” is used primarily as a recreational drug for its hallucinogenic effects. PCP is commonly taken orally, by inhalation, by insufflation or intravenously. It is well absorbed following all routes of administration, concentrating fastest in fatty tissues and the brain. Unchanged PCP is excreted in the urine in moderate amounts (10% of the dose). The terminal half-life for PCP varies considerably, with a range of 8 - 55 hours, averaging of 18 hours. The effects of PCP are unpredictable and variable. Depending on the amount used, the user may show signs of euphoria, relaxation, increased strength, time and space distortions, anxiety, panic, and hallucination.

Urine based screening tests for drugs of abuse range from complex analytical procedures to simple immunoassay tests. The sensitivity and rapidity of the immunoassays have made them the most accepted method of preliminary screening for drugs of abuse in urine. This allows the laboratory to eliminate the large number of negative specimens and focus on the smaller number of initially positive specimens.

Principles of the Procedure

The QuickScreen™ One Step Phencyclidine Test is a competitive immunoassay that is used to screen for the presence of Phencyclidine in urine. It is a chromatographic absorbent device in which drugs or drug metabolites in a sample compete with drug / protein conjugate immobilized on a porous membrane for a limited number of antibody /dye conjugate binding sites. The test device employs a unique combination of monoclonal and polyclonal antibodies to selectively identify Phencyclidine in urine with a high degree of confidence.

In the assay procedure, a urine sample is added to the test device in the Sample Well “S,” where it is absorbed into the device by capillary action. The urine mixes with the antibody-dye conjugate and flows across the pre-coated membrane. **When sample PCP levels are below 25 ng/mL** (the detection sensitivity of the test), antibody / dye conjugate binds to the drug / protein conjugate immobilized in the Test Region (T) of the device. This produces a colored Test Band that, *regardless of its intensity*, indicates a negative result.

When sample PCP levels are at or above 25 ng/mL, the free drug in the sample binds to the antibody / dye conjugate, preventing the antibody / dye conjugate from binding to the drug / protein conjugate immobilized in the Test Region (T) of the device. This prevents the development of a distinct colored band, indicating a potentially positive sample.

In either case, a colored Control Band is produced in the Control Region (C) by a non-specific antibody-dye / conjugate reaction. This band serves as a built-in quality control device that demonstrates antibody recognition and reactivity as well as confirmation that the test is complete.

Reagents & Materials Supplied

1. 25 Test Devices (Cat. # 9131) containing:
 - a. Monoclonal anti-PCP antibody / colloidal gold conjugate in a protein matrix containing 0.1% sodium azide coated in the sample path
 - b. PCP derivative / protein conjugate immobilized as a line in the test region
 - c. Goat anti-mouse antibody immobilized as a line in the control region
2. Directional Insert (Cat. # 9131-DI)
3. (Optional) Single Specimen Collection Kit (Cat. # 9501 or equivalent) – or –
4. (Optional) Split Specimen Collection Kit (Cat. # 9502 or equivalent)

Note: In addition to the materials supplied, a clock or other suitable timer is required.

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Warnings & Precautions

1. FOR IN VITRO DIAGNOSTIC USE ONLY.
2. For Professional use only.
3. Urine samples have the potential to be infectious. Follow Universal Precautions for proper handling and disposal methods.
4. Do not use this kit beyond its expiration date.
5. This method has been established using urine only. Other fluids have not been evaluated.
6. Do not reuse the Test Device.

Storage & Handling Requirements

Store at room temperature (15-28 °C). Do not freeze. Refer to expiration date for stability.

Sample Collection & Preparation

A fresh urine sample should be collected in one of the above-mentioned specimen collection kit or equivalent. Alternately, a clean, dry plastic or glass container, unused and without preservatives, may be used for specimen collection. Testing requires at least 1/2-inch (50 to 60 mL) of urine in the sample container. If required by your procedure, aliquot a portion of urine into the split sample container for later confirmation of results. If not required, dispose of all but 1/2-inch of urine and save the remainder for the QuickScreen™ test.

Samples may be tested immediately or stored for up to 48 hours at 2-8 °C. For longer storage, freeze samples at -20 °C or below.

Assay Procedure

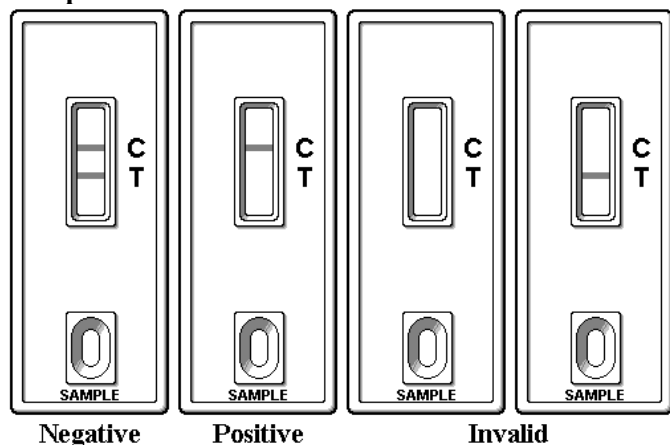
Preparation

1. Confirm that all samples and test components are at room temperature (15-28 °C) before testing.
2. Do not break seal on the foil pouch until you are ready to perform the test.

Testing

1. Open the foil pouch at the notch, remove the test device, and place it on a clean, level surface.
2. Hold the transfer pipette vertically and dispense 4 full drops of urine into the Sample Well "S" of the test device. Wait 5 seconds between adding each drop.
3. Read the result immediately at ten (5) minutes. Results read after 15 minutes have elapsed should be considered invalid.
- 4.

Interpretation of Test Results



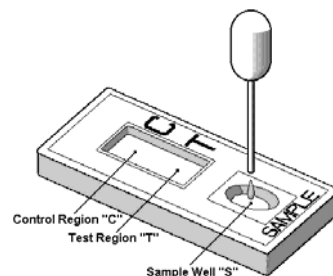
Positive – A positive result is indicated when only one (1) colored band appears in the Control Region (C) and no band appears in the Test Region (T). This result indicates a PCP level that is at or above the detection sensitivity of 25 ng/mL.

Negative – A negative result is indicated when two (2) colored bands appear, one in the Control Region (C) and one in the Test Region (T). This result indicates a PCP level that is below the detection sensitivity of 25 ng/mL.

Invalid – A test must be considered invalid if no bands appear or if a band appears in the Test Region without a Control Band. The presence of a Control Band is necessary to confirm assay performance.

Quality Control

An internal procedural control line has been incorporated into the test device to help ensure proper kit performance and reliability. However, the use of external controls is recommended. Positive and negative controls within 25% of the cutoff concentration should produce the expected results. For positive controls, only one (1) colored band will appear in the Control Region (C), and no band will appear in the Test Region (T). For negative controls, two (2) colored bands will appear, one in the Control Region (C) and one in the Test Region (T).



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Limitations of the Procedure

1. The possibility exists that substances and factors not described in this directional insert may interfere with the test, causing false results (e.g., technical or procedural error).
2. This test has been developed for testing urine samples only. The performance of this test using other specimens has not been substantiated.
3. Adulterated urine samples may produce erroneous results.
4. Strong oxidizing agents such as bleach (hypochlorite) can oxidize drug analytes. If a sample is suspected of being adulterated, obtain a new sample.
5. All positive samples must be confirmed by another method. Gas chromatography / mass spectrometry (GC/MS) is the method of choice to confirm the presence and concentration of a drug in urine.
6. This test is a qualitative, competitive screening assay. It is not designed to determine the quantitative concentration of Phencyclidine or the level of intoxication.
7. Because the QuickScreen™ Test is a competitive assay, no prozone effect is present.
8. Occasionally, samples containing Phencyclidine levels below the cutoff sensitivity for the test may produce a positive result.

Performance Characteristics

Sensitivity – The QuickScreen™ Phencyclidine Test detects PCP at a cutoff concentration equal to or greater than 25 ng/mL. The sensitivity of the QuickScreen™ Test was evaluated on 120 urine samples and compared with both commercially available immunoassays and GC/MS. At a cutoff of 25 ng/mL, an accuracy of 98% was observed.

Specificity – In three separate laboratory studies, including 2 clinical trials, a specificity of greater than 99% (70/70) was observed when compared to commercially available tests.

Accuracy – The accuracy of the QuickScreen™ Phencyclidine Screening Test was evaluated on 120 urine samples and compared with two commercially available immunoassays using the 25 ng/mL cutoff. An agreement of greater than 97% was observed. In addition, studies at 2 separate, independent clinical laboratories produced an agreement of greater than 98% (59/60) accuracy when compared to the Emit II assay.

Precision – Eight urine pools ranging from 0 to 190 ng/mL were assayed twice a day for twenty days. The results were interpreted individually by two technicians. The inter- and intra-assay coefficients of variation were less than 1% for all samples.

Cross-Reactivity – The following structurally related compounds were spiked into normal human urine and found to cross-react in the QuickScreen™ Phencyclidine Test. The results, in µg/mL, are expressed as that amount of compound capable of giving a result equivalent to 25 ng/ml Phencyclidine.

<i>N</i> -Acetylprocainamide	1000	Ketamine	500	Phencyclidine	0.025
Amitriptyline	1000	Labetalol	1500	(R)-(+)- α -Phenylethylamine	1000
(+)-Chlorpheniramine	500	Levorphanol	1000	(\pm)- α -Phenylethylamine	1000
(\pm)-Chlorpheniramine	750	Meperidine	1000	Promazine	1000
Cyclizine	1000	Methylphenidate	1000	Pyrimidine	800
Doxylamine	1200	Nomifensine	2000	Quinine	750
EDDP	25	Orphenadrine	1000	<i>dl</i> -Trihexyphenidyl	250
(\pm)-Isoproterenol	1200	Oxycodone	1000	Triprolidine	1000
(-)-Isoproterenol	1000				

Interfering Substances – The following compounds were spiked into normal human urine and tested for interference with the QuickScreen™ Phencyclidine Test. Unless otherwise noted, these compounds were tested to 100,000 ng/mL with no interference observed.

Acetone • Acetylsalicylic Acid (Aspirin) • Albumin • Alphenal • Alprazolam^[A] • Amantadine • (+)-Amethopterin • Amikacin • *dl*-Aminoglutethimide • Aminopyrine • Amobarbital • Amoxicillin • *d*, *dl* & *l*-Amphetamine • Ampicillin • Apomorphine • Aprobarbital • (-)-Arterenol • *l*-Ascorbic Acid (Vitamin C) • Aspartame • *d*, *dl* & *l*-Aspartic Acid • Atropine • Barbitol • Barbituric Acid • Benzoic Acid • Benzoylcegonine • Benzphetamine • Benztrapine Methane Sulfonate • Bilirubin • Bromazepam • Bromocriptine Mesylate • (+)-Brompheniramine •

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Butabarbital • Butalbital • Butethal • Caffeine • Cannabidiol • Cannabinol • Carbamazepine • Cephalixin • Chloramphenicol • Chlordiazepoxide • Chloroquine • Chlorpromazine • Chlorpropamide • Chlorprothixene • Cimetidine • Clemastine • Clomipramine • Clonazepam • Clonidine • Cocaine • Codeine • (–)-Cotinine • Creatinine • Cyclobenzaprine • Cyclosporin A • Cyproheptadine • (–)-Deoxyephedrine • Desipramine • Desmethyldiazepam • Dextromethorphan • 5,5-Diallylbarbituric Acid • Diazepam • Diflunisal • Digoxin • 4-Dimethylaminoantipyrine • Diphenhydramine • Diphenoxylate • 5,5-Diphenylhydantoin • Disopyramide • Doxepin • (+)- ψ & (–)- ψ -Ephedrine • (+), (±) & (–)-Ephedrine • (±) & (–)-Epinephrine • Erythromycin • Estriol • Estrone-3-Sulfate • Ethanol • Ethosuximide • Ethyl-*p*-Aminobenzoate • Ethylmorphine^[B] • Fenfluramine • Fenpropfen • Fentanyl^[B] • Flunitrazepam • Flurazepam • Furosemide • Gentamicin • Gentisic Acid • Glucose • *dl*-Glutethimide • Griseofulvin • Guaiacol Glyceryl Ester • Human Hemoglobin • Heroin^[B] • Hexobarbital • Hydrochlorothiazide • Hydrocodone • Hydromorphone • *o*-Hydroxyhippuric Acid • 5-Hydroxyindole-3-Acetic Acid • 5-Hydroxyindole-2-Carboxylic Acid • 11-Hydroxy- Δ^9 -THC^[C] • 3-Hydroxytyramine • Hydroxyzine • Ibuprofen • Imipramine • Indole-3-Acetic Acid • Indole-3-Butyric Acid • Indomethacin • (+)-Isoproterenol • Isoxsuprine • Kanamycin • Ketoprofen • Lidocaine • Lithium Carbonate • (±)-Lorazepam • Lormetazepam • Lysergic Acid Diethylamide (LSD)^[D] • Medazepam • Melanin • Mephentermine • Meprobamate • Mescaline • *dl*-Metanephine • (±)-Methadone • (+)-Methamphetamine • Methaqualone • (S)-6-Methoxy- α -Methyl-2-Naphthaleneacetic Acid • 2-Methyl-3-(3,4-Dihydroxyphenyl)-*dl* & *l*-Alanine • (±)-3,4-Methylenedioxyamphetamine • (±)-3,4-Methylenedioxymethamphetamine • Methypylon • Metoclopramide • (±)-Metoprolol • Morphine • Morphine-3- β -D-Glucuronide • Nafcillin • Nalorphine • Naloxone • Naltrexone • Naphazoline • α & β -Naphthaleneacetic Acid • Naproxen • Netilmicin • Niacinamide • Nialamide • Nicotinic Acid • Nifedipine • Nitrazepam • Norcodeine • Nordoxepin^[B] • Norethindrone • Normorphine^[B] • 11-Nor- Δ^8 & Δ^9 -THC-9-Carboxylic Acid^[C] • Nortriptyline • Noscipine • Nyldrin • Oxalic Acid • Oxazepam • Oxymetazoline • Papaverine • Penicillin G • Pentazocine • Pentobarbital • Phenelzine • Pheniramine • Phenobarbital • Phenothiazine • Phentermine • Phenylacetone • *l*-Phenylalanine • Phenylbutazone • *trans*-2-Phenylcyclopropylamine • *l*-Phenylephrine • β -Phenylethylamine • (±)-Phenylpropanolamine • Piroxicam • Potassium Chloride • Prazepam • Prednisolone • Primidone • Procainamide • Procaine • Prochlorperazine • Promethazine • (+)-Propoxyphene • 2-Propylpentanoic Acid • Protriptyline • Quinidine • Ranitidine • Riboflavin • (–)-Scopolamine • Secobarbital • Sodium Chloride • Sulindac • Temazepam • Terbutaline • Tetracycline • Tetraethylthiuram Disulfide • Δ^8 & Δ^9 -Tetrahydrocannabinol • Tetrahydrozoline • Thebaine • Theophylline • Thioridazine • *cis*-Thiothixene • Tobramycin • Triamterene • Triazolam^[B] • Trifluoperazine • Triflupromazine • Trimethobenzamide • Trimethoprim • Trimipramine • Tyramine • Urea • Uric Acid • Vancomycin • (±)-Verapamil • Zomepirac

^[A]No interference was observed when the compound was tested to 25 µg/mL.

^[B]No interference was observed when the compound was tested to 10 µg/mL.

^[C]No interference was observed when the compound was tested to 5 µg/mL.

^[D]No interference was observed when the compound was tested to 2.5 µg/mL.

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