QuickScreen™ PCP Test (RAP-2832)

IVD

Revised 30 Jan. 2006

Intended Use
The QuickScreen One Step Phencyclidine 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 of 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 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 and Explanation of the Test
Phencyclidine, commonly known as PCP or "angel dust", is used primarily as a recreational drug for its hallucinogenic effect. PCP is commonly taken orally, by inhalation, by insufflation or intravenously. It is well absorbed following all routes of administration, concerning 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.

Principles of the Procedure
QuickScreen™ One Step PCP Screening 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 PCP in urine with a high degree of confidence.

A test strip is inserted into a sample cup containing the urine specimen. The urine then migrates up the strip by capillary action. As it migrates it mixes with labeled antibody/dye mixture. When no PCP is present in a sample, or the PCP concentration is below 25 ng/ml (the detection sensitivity of the test), antibody/dye conjugate binds to drug/protein conjugate coated in the Test Region (T) of the device. This reaction produces a color5ed Test Band which*, regardless of its intensity*, indicates a negative result.

When the PCP urine concentration is **at or above 25 ng/ml**, antibody/dye conjugate binds to free drug, competing with the drug/protein conjugate in the test region (T) of the device for the limited number of antibody binding sites. 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, demonstrating generic antibody recognition and reactivity as well as confirming that the test result is valid.

Reagents & Materials Supplied

1. **50 Test Devices:**
   a) Each device contains mouse anti-PCP-antibody/dye conjugate (in a protein matrix with 0.1% sodium azide) coated in the sample path. As an internal control, goat anti-mouse is immobilized in the Control Region. As urine migrates it transports the anti-PCP/dye conjugate up the membrane. The mouse anti-PCP/dye conjugate binds to the immobilized goat anti-mouse.

2. Directional Insert

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 and Handling Requirement

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

Sample Collection and Preparation

A fresh urine sample should be collected in a clean, dry plastic or glass container. The container should not have been used previously or contain preservatives. 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 the seal on the foil pouch until you are ready to perform the test.

Testing

1. Open the foil pouch at the notch and remove the test device. Take care not to touch the exposed membrane.
2. Insert the reactive end of the test device into the urine sample. DO NOT immerse the device any deeper into the sample than the maximum level indicated by the line on the device label.
3. Read the results immediately within max.10 (ten) minutes.
4. Attention: Results read after 10 minutes have elapsed and should be considered invalid.

Interpretation of Test Result

Negative: A Negative result is indicated by the appearance two (**2**) colored bands, one in the control region (**C**) and one in the test region (**T**). This result indicates that either there is no Phencyclidine present in the sample, or that it is present at a level below 25 ng/ml.

Positive: A Positive result is indicated by the appearance of only one (**1**) colored band in the Control Region (**C**) with no colored band seen in the Test Region (**T**). This result indicates a Phencyclidine level at or above 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 result. For positive controls, only one (**1**) colored band will appear within the Control Region (**C**), with no band seen within the Test Region (**T**). For negative controls, two (**2**) colored bands will develop, one in the Control Region (**C**) and one in the Test Region (**T**).

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 metabolites or the level of intoxication. Because it is a competitive assay, no prozone effect is present.
7. Because the QuickScreen is a competitive assay, no prozone effect is present.
8. Occasionally, samples containing Phencyclidine levels below the cut-off sensitivity for the test may produce a positive result.

Performance Characteristics

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 97% was observed. In addition, studies at 2 separate, independent clinical laboratories produced an agreement of 59/60, or >98% accuracy, when compared to the Emit II assay.

Specificity:
In three separate laboratory studies, including 2 clinical trials, a specificity of 70/70, or >99% was observed when compared to commercially available tests.

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

Cross-Reactivity: The following structurally related compounds were prepared in normal human urine, tested and found to cross-react with the QuickScreen Phencyclidine Test. The results are expressed as the amount of compound capable of producing a result equivalent to 25 ng/ml of Methadone. All results are expressed as µg/ml concentrations.

N-Acetylprocainamide 1000	Ketamine 500	Phencyclidine 0.025
Amitriptyline 1000	Labetalol 1500	(R)-(+)-a-Phenylethylamine 1000
(+)-Chlorpheniramine 500	Levorphanol 1000	(±)-a-Phenylethylamine 1000
(±)-Chrlorpheniramine 750	Meperidine 1000	Promazine 1000
Cyclizine 1000	Methylphenidate 1000	Pyrilamine 800
Doxylamine 1200	Nomifensine 2000	Quinine 750
EDDP 25	Orphenadrine 1000	dl-Trihexyphenidyl 250
(±)-Isoproterenol 1200	Oxycodone 1000	Triprolidine 1000

(-)-Isoproterenol 1000		

Bibliography

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Interfering Substances

The following compounds were prepared in normal human urine and tested to 100 µg/ml 8except were noted), and exhibited no interference:

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 – Barbital - Barbituric Acid – Benzoic Acid – Benzoylecgonine – Benzphetamine – Benztropine Methane Sulfonate – Bilirubin – Bromazepam - Bromocriptine Mesylate – (+)-Brompheniramine – Butarbital - Butalbital - Butethal - Caffeine - Cannabidiol – Cannabinol - Carbamazepine – Cephalexin – 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-Diallylbarbituratic Acid - Diazepam – Diflunisal – Digoxin – Diphenhydramine – 4-Dimethyl-aminoantipyrine - Diphenoxylate – 5,5-Dipenylhydantoin – Disopyramide – Doxepin – (+) & (-)-ψ-Ephedrine - (+),(±) & (-)-Ephedrine – (±) & (-)-Epinephrine – Erythromycin – Estriol – Estrone-3-Sulfate – Ethosuximide – Ethylmorphine[(B)] - Ethyl-*p*-Aminobenzoate – Fenfluramine – Fenoprofen - Fentanyl[[B]] - Flunitrazepam – Flurazepam – Furosemide – Gentamicin – Gentisic Acid - Glucose– *dl*-Glutethimide – Griseofulvin – Guaiacol Glyceryl Ester - Hemoglobin- Heroin[(B)] - Hexobarbital - Hydrochlorothiazide - Hydrocodone - Hydromorphone - *... continued list available on request.*

[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