QuickScreen™ Pro Multi Drug Screening Test I (RAP-3002)

Revised 30 Jan. 2006

Intended Use

The cutoff concentrations for this test are: Phencyclidine, 25 ng/ml; Amphetamine, 1000 ng/ml; THC, 50 ng/ml; Cocaine (Benzoylecgonine), 300 ng/ml; and Opiates, 300 ng/ml. This assay is intended for use in clinical toxicology laboratories, Physicians' offices, drug of abuse clinics, law enforcement agencies and on-site workplace drug testing programs.

This test provides only a preliminary test result. A more specific alternate test 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 and Explanation of the Test

Phencyclidine (or PCP), also known as "Angel Dust", is used primarily as a recreational drug for its hallucinogenic effects. PCP is commonly taken orally, by inhalation, by sufflation or intravenously. It is weill absorbed by all routes of administration, concentrating festest in fatty tissues and in the brain. Unchanged PCP is excreted in the urine in moderate amounts (10% of the dose). The terminal half-life for PCP varies considerably, ranging from 8 to 55 hours, averaging 18 hours. The effects of this drug are unpredictable and variable. Users may exhibit signs of euphoria, anxiety, relaxation, increased strength, time and space distortions, panic and hallucination.

Amphetamine and its metabolites are central nervous system stimulants whose pharmacological properties include alertness, wakefulness, increased energy, reduced hunger and an overall feeling of well-being. Large doses and extended usage can result in higher tolerance levels and physiological dependency. Both D and L forms of amphetamine are controlled substances.

Δ^9-Tetrahydrocannabinol (THC) is generally accepted to be the principle active component in marijuana and hashish, although other cannabinoids are likely to contribute to their physiological activity. THC is rapidly absorbed by inhalation and by the gastrointestinal tract, and is almost completely metabolized. Its predominant metabolite is 11-Nor-Δ^9-THC-Δ^9-carboxylic acid (or THCA), which is found in the plasma, feces and urine along with other compounds. Very low concentrations of THC may be detected in urine during the initial several hours, but THCA persists in urine at a detectable concentration for many days after smoking.

Cocaine is an alkaloid present in coca leaves (erythyroxine coca) whose pharmacological properties include alertness, wakefulness, increased energy and an overall feeling of euphoria. Cocaine has been used medicinally as a local anesthetic, however, its adictive properties have minimized its modern value as an anesthetic. Elimination of cocaine is predominantly controlled by its biotransformation; it is almost completely metabolized to benzoylecgonine. Very low concentration of cocaine may be detected in urine during the initial several hours, but enzoylecgonine persists in urine at detectable concentrations for 48 hours.

Opiates are any of the addictive, narcotic, pain-relieving drugs derived from the opium poppy (Papaver somniferum). An opiate is any natural or synthetic drug that has morphine-like pharmacological actions. Opiates include morphine, heroine, codeine and nalorphine.

Urine-based screening tests for drugs of abuse range from complex analytical procedures to simple immunoassay tests. The sensitivity and rapidity of the immonoassay 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 samples. The QuickScreen™ Pro Multi Drug Screening Test is a competitive multi-panel immunoassay used to rapidly screen for the presence of drugs or drug metabolites in urine.

Principles of the Procedure

QuickScreen™ Pro Multi Drug Screening Test is a chromatographic absorbent device in which drug compounds in a sample compete with drug / protein conjugate immobilized on a porous membrane for limited numbers of binding sites. The test device employs unique combinations of monoclonal and polyclonal antibodies to selectively identify drug compounds in urine with a high degree of confidence.
A test device is inserted into a sample cup containing the urine specimen. The urine then migrates up the device by phoresis, mixing with antibody / dye conjugate. When a target drug concentration is below cutoff (the detection sensitivity of a test panel), unbound antibody / dye conjugate binds to immobilized drug / protein conjugate in the Test Region (T) of the respective test panel, producing a colored Test Band which, regardless of its intensity, indicates a negative result. When a target drug is present in the sample at a concentration at or above cutoff, the antibody / dye conjugate binds the free drug, forming a complex which competes with the drug / protein conjugate immobilized in the Test Region (T) of the respective test panel. This prevents the development of the colored Test Band, indicating a potentially positive result. In either case, a colored Control Band is produced in the Control Region (C) by a non-specific sandwich dye / conjugate reaction. This band serves as a built-in quality control feature, demonstrating antibody recognition and reactivity as well as confirming that the procedure is complete.

Reagents & Materials Supplied

1. **25 Test Devices:** Each test device contains 5 separate panels, one for each target drug of abuse. Each panel contains a drug / protein conjugate coated in the Test Region, and goat anti-mouse IgG / dye coated in the Control Region. A mixture of anti-drug / dye conjugate and mouse IgG / dye conjugate, in a protein matrix containing 0.1% sodium azide, is coated in the sample path.
2. Directional Insert

Materials Required But Not Supplied

1. Clock or other suitable timer.
2. Plastic or glass container for sample collection. If required, use a split container.

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.

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Storage and Handling Requirement

This kit is to be stored 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. A lean, dry plastic or glass container, unused and without preservatives, may be used for specimen collection. Testing requires at least ½ inch (50-60 ml) of urine in the sample container. If required by your procedure, aliquot a portion of urine into a split sample container for later confirmation of results. If not required, dispose of all but ½ inch of urine and save the reminder 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

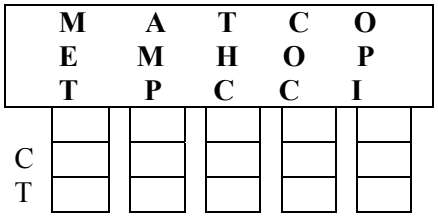
Preparation
1. Confirm that all samples and test components are at room temperature (15-28°C) before testing.
2. Do not break the seal on the foil pouch until you are ready to perform the test.

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 and of the test device into the urine sample. Make sure that the urine level is not above the "MAX URINE LEVEL" printed on the front of the device. Leave the test device in the sample cup.
3. Read the result immediately at ten (10) minutes. Results read after 15 minutes have elapsed should be considered invalid.

Interpretation of Test Results

Negative Test Results for all drugs tested

Negative: A Negative result is indicated by the appearance of two (2) colored bands, on in the Control Region and one in the Test Region, indicating that the target drug being tested for is not present in the urine sample. Some negative results may appear in as little as 1 minute:



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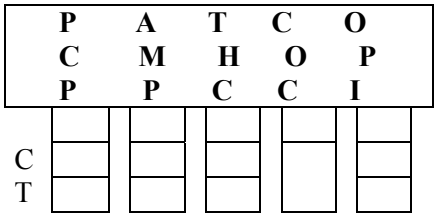
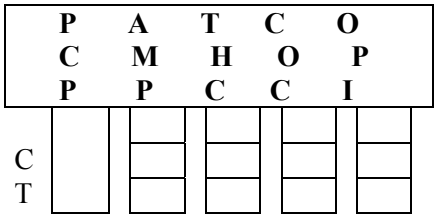
Positive Test Results for Cocaine

Positive: A Positive result is indicated by the appearance of one (1) colored band in the Control Region, with no band seen in the Test Region. This result indicates that a drug of abuse, at or near cutoff concentration, is present in the urine sample More than one test panel may be Positive. Potentially positive results can only be confirmed after a full 10 minutes have passed.



Invalid Test Results for PCP and THC

Invalid: A test must be considered Invalid if no bands appear 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 band has been incorporated into the test device to help ensure proper kit performance and reliability. However, using external controls is recommended. Positive and negative controls, within 25% of the cutoff concentration should produce the expected result. For positive controls, a single colored band should appear in the Control Region, with no band in the Test Region. For negative controls, two colored bands should appear, one in the Test Region and one in the Control Region.

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, a new sample must be obtained.
5. All positive samples must be confirmed by another method. GC/MS is the method of choice to confirm the presence and concentration of a drug urine.

6. This test is a qualitative screening assay. It is not designed to determine the quantitative concentration of the target drugs or the level of intoxication.
7. Because QuickScreen™ is a competitive assay no prozone effect is present.

Performance Characteristics

Sensitivity: The sensitivity of the QuickScreen™ Pro Multi Drug Screening Test was evaluated on clinical (urine) samples and compared to a commercially available immunoassay at the cutoff concentrations. The combined studies of 2 independent clinical laboratories are also reported for sensitivity, comparing QuickScreen™ to the Emit II instrument-based immunoassay.

Specificity: The specificity of the QuickScreen™ Pro Multi Drug Screening Test was evaluated on clinical (urine) samples and compared to a commercially available immunoassay at the cutoff concentrations. The combined studies of 2 independent studies of 2 independent clinical laboratories are also reported for specificity, comparing QuickScreen™ to the Emit II assay.

Accuracy: The accuracy of the QuickScreen™ Pro Multi Drug Screening Test was evaluated on clinical (urine) samples and compared to a commercially available immunoassay at the cutoff concentrations. the combined studies of 2 independent clinical laboratories are also reported for accuracy, comparing QuickScreen™ to the Emit II assay.

	In-House Study, % Agreement					Clinical Study, % Agreement				
	PCP	**AMP**	**THC**	**COC**	**OPI**	**PCP**	**AMP**	**THC**	**COC**	**OPI**
n =	167	189	143	164	176	140	124	102	143	151
Sensitivity	99	97.6	99	100	>99	95	98.8	98	100	>99
Specificity	99	100	99	95.9	>99	99	100	99	87.5[(A)]	>99
Accuracy	>99	99.4	98	98.1	>99	97.9	99.2	>98	96.5	>99

[(A)]Five Discrepant results were in the Cocaine Clinical Study; 5 samples were from 3 to 10% below the assay cutoff concentrations (271 to 293 ng/ml) and subsequently tested positive by GC/MS.

Precision: 8 urine pools ranging in concentration from 0 to 200% of cutoff were assayed twice a day for 20 days. The results were individually interpreted by 2 technicians. The inter- and intra-assay coefficients of variation were determined to be >98%.

Interfering Substances: The following compounds were prepared in normal human urine and tested for cross-reactivity with the QuickScreen™ Pro Multi Drug Screening Test. The results (in µg/ml) are that amount of compound capable of giving a result equivalent to the target drug at cutoff concentration. A blank space indicates no interference was observed to 100 µg/ml.

Chemical Analyte	**PCP**	**AMP**	**THC**	**COC**	**OPI**
Acetaminophen, Acetone, Acetyslicylic Acid, Albumin, Alphenal, Amantadine					
***N*-Acethylprocainamide, (+)Ψ-Ephedrine, (±)-**	**1000**				

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Ephedrine					
Alprazolam	25 (B)	25 (B)	25 (B)	25 (B)	25 (B)
(+)Amethopterin; Amikacin, dl-Aminoglutethimide; Aminopyrine; Amobarbital					
Amoxicillin; Ampicillin; Apomorphine; Aprobarbital; (-)-Arterenol; Aspartame					
***d*-Amphetamine**		**1**			
***dl*-Amphetamine, 3-Hydroxytyramine; ß-Phenylethylamine**		**10**			
***l*-Amphetamine; Mephentermine**		**100**			
l-Ascorbic Acid; d,dl,l-Adpartic Acid; Atropine; Barbituric Acid					
Barbital; Benzoic Acid; Benzphetamine; Benztropine Methane Sulfonate; Bilirubin;					
Benzoylecgonine; Cocaine				**0.3**	
Bromazepam; Bromocriptine Mesylate; (+).Brompheniramine; Butabarbital					
Butalbital; Butethal; Caffeine; Cannabidiol; Cannabinol; Carbarnazepine;					
Cephalexin; Chlorampenicol; Chlordiazepoxide;					
Chloroquine; Chlorpromazine; Chlorpropamide; Chlorprothixene					
Cimetidine; Clemastine; Clonazepam, Clomipramine; Clonidine; (-)-Cotinine; Creatinine;					
(+)-Chlorpheniramine; Ketamine	500				
(+)-Chlorpheniramine	750				
Codeine; Morphine; Morphine 3-β-D-Glucuronide					**0.3**
Cyclobenzaprine; Cyclosporin A; Cyprohepadine; (-)-Deoxyephedrine; Desipramine;					
Desmethyldiazepam; 5,5-Diallylbarbituric Acid; Diflunisal; Digoxin					
Dextromethorphan					**50**
Diazepam; 4-Dimethylaminoantipyrine; Diphenhydramine; 5,5-Diphenylhydantoin					
Doxylamine; (±)-Isoprotenerol	**1200**				
Diphenoxylate; Disopyramide; Doxepin, (+),(-)-ψ-Ephedrine; (+),(±),(-)-Ephedrine; (±)-Epinephrine; Erythromycin; Estriol; Estrone-3-Sulfate; Ethosuximide					
2-Ethylidene-1,5-Dimethyl-3,3-Diphenylpyrrolidine (EDDP)	**25**				
Ethylmorphine	10 (C)	10 (C)	10 (C)	10 (C)	**0.35**
Ethanol; Ethyl-p-Aminobenzoate; Fenfluramine; Fenoprofen; Flunitrazepam					
Fentanyl	**10 (C)**	**10 (C)**	**10 (C)**	**10 (C)**	**10 (C)**

Flurazepam; Furonsemide; Gentamicin; Gentisic Acid; Glucose; dl-Glutethimide					

(B) Tested to 25 µg/ml with no interference observed.
(C) Tested to 10 µg/ml with no interference observed.

Chemical Analyte	MET	AMP	THC	COC	OPI
Griseofulvin; Guaiacol Glyceryl Ester; Hemoglobin; Hexobarbital; Hydroxyzine					
Heroin	10 (C)	10 (C)	10 (C)	10 (C)	**0.3**
Hydrocodone; Hydromorphone; Naloxone					**0.4**
Hydrochlorothiazide; o-Hydroxyhippuric Acid; 5-Hydroxyindole-3-Acetic Acid					
11-Hydroxy-Δ^9-THC	5 (D)	5 (D)	**1**	5 (D)	5 (D)
5-Hydroxyindole-2-Carboxylic Acid; Indomethacin; Indole-3-Butyric, Acetic Acid					
Ibuprofen; Imipramine;(+), (-)-Isoproterenol; Isoxsuprine					
Kanamycin; Ketoprofen; Lidocaine, Lithium Carbonate					
Labetalol	**1500**				
Levorphanol	**1000**				
Lysergic Acid Diethylamide	2.5 (E)	2.5 (E)	2.5 (E)	2.5 (E)	2.5 (E)
(±)-Lorazepam; Lormetazepam; Meprobamate; Melanin					
Meperidine; Methylphenidate; Orphenadrine; Promazine; Triprolidine	**1000**				
Medazepam; Mescalin; dl-Metanephrine; (±)-Methadone; (+)-Metamphetamine					
Methaqualone; (s)-6-Methoxy-α-Methyl-2-Naphtaleneacetic Acid; Methyprylon					
2-Methyl-3-(3,4-Dihydorxyphenyl)-dl, l-Alanine; (±)-Methylenedioxymethamphetamine					
(±)-3,4-Methylenedioxyamphetamine		**4.5**			
Metoclopramide				**25**	
(±)-Metoprolol; Nafcillin; Naphazoline, a,ß-Naphtaleneacetic Acid; Naproxen					
Nalorphine; Norcodeine					**0.5**
Naltrexone					**5**
Netilmicin; Niacinamide; Nialamide; Nicotiinc Acid					
Nifedipine; Norethindrone					
Nomifensine	**2000**				
11-Nor-Δ^8-TCH-9-Carboxylic Acid	5 (D)	5 (D)	**0.1**	5 (D)	5 (D)
11-Nor-Δ^9-TCH-9-Carboxylic Acid	5 (D)	5 (D)	**0.05**	5 (D)	5 (D)

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Nordoxepin	10 (C)	10 (C)	10 (C)	10 (C)	10 (C)
Normorphine	10 (C)	10 (C)	10 (C)	10 (C)	10 (C)
Nitrazepam; Nortryptiline; Noxcapine; Nylidrin; Oxalic Acid; Oxazepam; Oxymetazoline; Papaverine					
Oxycodone; Thebaine					**0.6**
Penicillin G; Pentazocine; Pentobarbital; Phenothiazine;					
Phencyclidine	**0.025**				
Phentermine		**200**			
Phenelzine; Pheniramine; Phenobarbital; Phenylacetone;					
(±)-Phenylpropanolamine; Phenylalanine; Phenylbutazone, trans-2-Phenylcyclopropylamine;					
(R)-(+)-∝-Phenylethylamine;	**1000**	**100**			
(±)-α-Phenylethylamine;	**1000**	**10**			
Piroxicam; Potassium Chloride; Prazepam; Prednisolone; Primidone; Procainamide					
Procaine				**100**	
Prochlorperazine; Promethazine; (+)-Propoxyphene; 2-Prpylpentanoic Acid; Protriptyline					
Pyrilamine	**800**			**100**	
Quinidine; Quinine, Ranitidine; Riboflavin, Secorbarbital					
(-)-Scopolamine; Sodium Chloride; Sulindac; Tetraethylthiuram Disulfide					
Temazepam, Terbutaline; Tetracycline; Tetrahydrozoline					
Δ^8-Tetrahydrocannabinol			**100**		
Δ^9-Tetrahydrocannabinol			**0.05**		
Theophylline; Tobramycin; Triamterene; Trimethobenzamide					
cis-Thiothixene; Trifluoperazine; Triflupromazine; Trimethoprim; Trimipramine					
dl-Trihexyphenidyl	**250**				
Triazolam	10 (C)	10 (C)	10 (C)	10 (C)	10 (C)
Tyramine		**12.5**			
Urea; Uric Acid; Vancomycin; (±)-Verpamil; Zomepriac					

Bibliography and Suggested References

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(D) Tested to 5 µg/ml with no inteference abserved.
(E) Tested to 2.5 µg/ml with no interference observed.