

QuickScreen™ Cup Multi Drug Screening Test

With "Timer" / Catalog # 9298Z-25 / Test Instructions

Intended Use

The QuickScreen™ Cup Multi Drug Screening Test is a rapid, self-timed, qualitative immunoassay for the detection of drugs of abuse in urine. The cutoff concentrations for the test are Barbiturates at 200 ng/mL, Benzodiazepines at 200 ng/mL, Methadone at 300 ng/mL, Amphetamine at 1000 ng/mL, Methamphetamine at 500 ng/mL, Cocaine metabolite (Benzoylcegonine) at 300 ng/mL, THC metabolite (THCA) at 50 ng/mL, Opiates at 300 ng/mL, Oxycodone at 100 ng/mL and PCP at 25 ng/mL. This assay is intended for professional use.

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 & Explanation of the Test

Barbiturates (BAR) are a large class of abused pharmaceuticals that are anxiolytic, sedative/hypnotic, anti-convulsant and anesthetic drugs. As CNS depressants, barbiturates affect excitatory and inhibitory synaptic neurotransmission. Ultra short-acting barbiturates used for anesthesia, such as Pentobarbital, depress excitatory neuronal transmission to a greater extent than anti-convulsant barbiturates such as Phenobarbital. Barbiturates are rapidly and completely absorbed with nearly 100% bioavailability. Short-acting barbiturates are primarily excreted in urine as metabolites, while long-acting barbiturates are primarily excreted unchanged. Ratios of drugs to metabolites excreted vary, dependent upon duration of action.

Benzodiazepines (BZD) are another large class of abused pharmaceuticals that are sedative/hypnotics and anti-anxiety drugs that produce calming effects; thus are often prescribed as tranquilizers. Frequently abused Benzodiazepines include Alprazolam (Xanax®), Diazepam (Valium®), Lorazepam (Ativan®), Triazolam (Halcion®), Chlordiazepoxide (Librium®), Flurazepam (Dalmare®) and Temazepam (Restoril®). A trend has been observed in recent years of abuse of these legitimate pharmaceuticals in conjunction with illicit controlled substances such as methadone and heroin. Benzodiazepines may be detected for up to 2 weeks in urine.

Methadone (MTD) is a long-acting synthetic opiate agonist clinically available in the U.S. since 1947. Acting on the central nervous and cardiovascular systems, producing respiratory and circulatory depression, Methadone also produces meiosis and increases the tone of smooth muscle in the lower gastrointestinal tract while decreasing the amplitude of contractions.

Amphetamine (AMP), Methamphetamine (MET) and their 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 and the (+) form of Methamphetamine are controlled substances.

Cocaine (COC) is an alkaloid present in coca leaves (*Erythroxine 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 addictive properties have minimized its modern value as an anesthetic. Elimination of Cocaine is predominantly controlled by its biotransformation to Benzoylcegonine. Very low concentrations of Cocaine may be detected in urine during the initial several hours, but Benzoylcegonine persists in urine at detectable concentrations for 48 hours.

Δ^9 -Tetrahydrocannabinol (THC) is generally accepted as the principle active component in marijuana and hashish, although other cannabinoids contribute to their physiological activity. THC is rapidly absorbed by inhalation and through the gastrointestinal tract, and is almost completely metabolized. Its predominant metabolite, 11-Nor- Δ^9 -Tetrahydrocannabinol-9-Carboxylic Acid, or THCA, 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 after smoking, but THCA persists in urine at a detectable concentration for many days.

Opiates (OPD) are addictive, pain-relieving narcotic drugs derived from the opium poppy (*Papaver somniferum*). An opiate is any natural or synthetic drug, derived from this plant, that has morphine-like pharmacological actions. Natural opiates include Morphine, Codeine and Thebaine. Synthetic opiates include Heroin, Hydrocodone and Levorphanol.

Oxycodone (OXY) is an effective analgesic for mild to moderate pain control, chronic pain syndromes, and for the treatment of terminal cancer pain. Five mg of Oxycodone is equivalent to 30 mg of codeine when administered orally. Oxycodone and morphine are equipotent for pain control in the normal population. Oxycodone is considered to be similar to morphine, in all respects, including its abuse & dependence liabilities.

Phencyclidine, also known as PCP or "angel dust," is used primarily as a recreational drug for its hallucinogenic effects. Commonly taken orally, by inhalation, by insufflation or intravenously, it is well-absorbed by 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). Terminal half-life varies considerably, ranging from 8 to 55 hours, though averaging 18. 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.

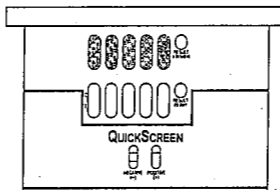
Urine based screening tests for drugs of abuse range from complex analytical procedures to simple immunoassay tests. The sensitivity and rapidity of immunoassays have made them the most accepted method of preliminary screening for drugs of abuse in urine. This allows the laboratory to eliminate the large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

Principle of the Procedure

The QuickScreen™ Cup Multi-Drug Screening Test is a competitive immunoassay that is used to screen for the presence of drugs of abuse 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 drugs of abuse in urine with a high degree of confidence. The test device also contains a self-timer that indicates when test results are ready to be interpreted.

In the procedure, a fresh urine sample is collected directly into the cup. The urine is absorbed into each test panel by capillary action, mixes with the antibody/dye conjugate, and flows across the pre-coated membrane.

When sample drug levels are below the target cutoff (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.



Reagents & Materials Supplied

- 25 Self-Timed Test Devices (Cat. # 9298Z); separate panels for each target drug contain:
 - Monoclonal anti-drug antibody / colloidal gold conjugate in a protein matrix containing 0.1% sodium azide coated in the sample path
 - Drug derivative / protein conjugate immobilized as a line in the Test Region (T)
 - Goat anti-mouse antibody immobilized as a line in the Control Region (C)
- Directional Insert (Cat. # 9298Z-DI)
- (Optional) Single Specimen Collection Kit (Cat. # 9501 or equivalent) – or –
- (Optional) Split Specimen Collection Kit (Cat. # 9502 or equivalent)

Warnings & Precautions

- FOR *IN VITRO* DIAGNOSTIC USE ONLY.
- For Professional use only.
- Urine samples have the potential to be infectious. Follow Universal Precautions for proper handling and disposal methods.
- Do not use this kit beyond its expiration date.
- This method is established using urine only. No other fluid has been evaluated.
- 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 the cup device immediately prior to testing. The urine should be collected to the recommended volume indicated by the "FILL TO HERE" mark on the outside of the cup.

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


- Confirm that the cup device is at room temperature (15–28 °C) before testing.
- Do not open the foil pouch until you are ready to perform the test.

Testing

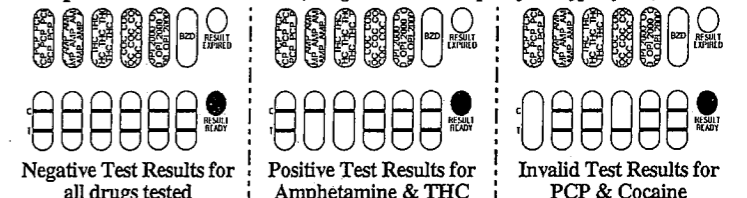
- Open the pouch at the tear notch, remove the cap from the test device and discard the desiccant packets.
- Have the donor collect his or her urine specimen in the cup to the recommended volume. Make sure that the urine level is at least at the "FILL TO HERE" mark printed on the front of the cup. Replace the cap and check the temperature strip to ensure that the temperature of the specimen is between 90° and 100° F.
- Read the test results when indicated (see When to Read Test Results Using the "Timer.")

When to Read Test Results Using the "Timer"

 When the "RESULT READY" window is completely filled with red color, or is almost completely covered with red color that reaches the top of the window, the test results are ready to interpret.

 When red color becomes clearly visible at the bottom of the "RESULT EXPIRED" window, test results should no longer be interpreted and should not be considered as conclusive.

Interpretation of Test Results (Images are an example of this type of test)



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), before any red color appears at the bottom of the "RESULT EXPIRED" window. This result indicates that the target drug is not present or its concentration is below the detection sensitivity of the test. More than one panel. Some negative results may appear in as little as 1 minute, and can be safely interpreted as soon as 2 colored bands are visible.

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), after a red spot appears in the "RESULT READY" window. This result indicates that the target drug concentration is at or above the detection sensitivity of the panel. More than one panel. Potentially positive results can only be reported when a red spot appears in the timer's "RESULT READY" window, and before any red color appears at the bottom of the timer's "RESULT EXPIRED" window.

Invalid – A test must be considered invalid if, after a red spot appears in the "RESULT READY" window, 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).

Limitations of the Procedure

- It is possible that substances and factors not described in this directional insert may interfere with the test, causing false results (e.g. technical or procedural error).
- This test has been developed for testing urine samples only. Its performance using other specimens has not been substantiated.
- Adulterated urine samples may produce erroneous results.

- 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.
- All preliminary positive results 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.
- This test is a qualitative screening assay. It is not designed to determine the quantitative concentration of target drugs or the level of intoxication.
- Because QuickScreen™ is a competitive assay no ozone effect is present.
- Occasionally, samples containing target drugs below the target drug's cutoff sensitivity for the test may produce a positive result.

Performance Characteristics

Sensitivity – The sensitivity of the QuickScreen™ Pro Multi Drug Screening Test was evaluated on clinical (urine) samples and compared with a commercially available immunoassay at the cutoff concentrations. In addition, the combined studies of two independent clinical laboratories are reported for overall 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 with a commercially available immunoassay at the cutoff concentrations. In addition, the combined studies of two independent clinical laboratories are reported, 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 with a commercially available immunoassay at the cutoff concentrations. In addition, the combined studies of two independent laboratories are reported, comparing QuickScreen to the Emit II assay.

Amphetamine			THC			Cocaine ¹			Opiates		
GC/MS			GC/MS			GC/MS			GC/MS		
9298Z	+	%	9298Z	+	%	9298Z	+	%	9298Z	+	%
+	83	98.39	+	102	>99	+	108	>99	+	116	>99
-	1	40	-	35		-	35		-	60	
MET-500			Oxycodone			Benzodiazepines			Methadone		
GC/MS			GC/MS			GC/MS			GC/MS		
9298Z	+	%	9298Z	+	%	9298Z	+	%	9298Z	+	%
+	116	97.34	+	98	>99	+	160	97.93	+	96	>99
-	5	67	-	0	94	-	0	124	-	2	109
Barbiturates			PCP								
GC/MS			GC/MS								
9298Z	+	%	9298Z	+	%						
+	50	97	+	84	98.6						
-		37	-	2	39						

¹Five discrepant results were observed in the Cocaine Clinical Study. The samples were from 3 to 10% below the assay cutoff concentration (271 to 293 ng/mL) and subsequently tested positive by GC/MS.

²Six samples at concentrations 3.5 to 9.2% below cutoff gave positive results in the Benzodiazepines Clinical study at site 2

Precision – Eight urine pools, ranging in concentration from 0 to 200% of cutoff, were assayed twice a day for 20 days. The results were interpreted individually by two technicians. The inter- and intra-assay coefficients of variation were determined to be less than 2%.

Cross-Reactivity – The following structurally related compounds were spiked into normal human urine and found to cross-react in the QuickScreen Pro Multi Drug Screening Test. The results, in µg/mL, are expressed as that amount of compound capable of giving a result equivalent to the target drug at its cutoff concentration. Unless otherwise noted, a blank space indicates no cross-reactivity was observed when the compound was tested at 100 µg/mL to the target drug at its cutoff concentration. Unless otherwise noted, a blank space indicates the compounds were tested to 100 µg/mL with no cross-reactivity observed.

Compound	BAR	BZD	MTD	AMP	MET	COC	THC	OPI	OXY	PCP
Amobarbital	0.15									
Aprobarbital	0.05									
Barbital • Butobarbital • Pentobarbital	0.025									
Butalbital	0.3									
Butethal	0.075									
5,5-Diallylbarbituric Acid	0.1									
Phenobarbital • Secobarbital	0.2									
(±)-Thiopental	9.5									
Alprazolam ^(A) • Clonazepam	0.5									
Bromazepam	0.6									
Chlordiazepoxide	0.3									
Desmethyldiazepam	0.75									
Diazepam • Flunitrazepam	0.4									
Flurazepam • Medazepam • Prazepam	1.0									
(±)-Lorazepam • Triazolam ^(B)	0.5									
Lormetazepam	0.4									
Nitrazepam • Oxazepam	0.2									
Temazepam	0.25									
(-) - α-Acetylmethadol (LAAM)				1						
(-) - α-Methadol				0.8						
(±)-Methadone				0.3						
<i>d</i> -Amphetamine					1					
<i>d</i> -Amphetamine • 3-Hydroxytyramine					10					
<i>l</i> -Amphetamine • (R)-(+)-α-Phenylethylamine					100					
Mephentermine					100	10				
(±)-3,4-Methylenedioxyamphetamine					4.5					
(±)-α-Phenylethylamine • β-Phenylethylamine					10					
Tyramine					12.5	62.5				
(-) - Deoxyephedrine					1					
Nylidrin					5					
(+) - Methamphetamine					0.5					
(±)-3,4-Methylenedioxymethamphetamine					3.5					
Benzoylcegonine • Cocaine						0.3				
Metoclopramide						25				
Procaine • Pyrilamine						100				
11-Hydroxy-Δ ⁹ -THC ^(C)							1			
11-Nor-Δ ⁸ -THC-9-Carboxylic Acid ^(C)							0.1			
11-Nor-Δ ⁹ -THC-9-Carboxylic Acid ^(C)							0.05			
Δ ⁸ -Tetrahydrocannabinol							100			
Δ ⁹ -Tetrahydrocannabinol							0.05			
Codeine								0.3	100	
Heroin ^(B)								0.3		
Dextromethorphan								50	0.5	
Ethylmorphine ^(B)								0.35	0.35	
Hydrocodone								0.4		
Hydromorphone								0.4		
Nalorphine								0.5	0.5	
Morphine								0.3	0.3	
Morphine-3-β-D-Glucuronide								0.3	0.3	
Naloxone								0.3	1.4	
Naltrexone								5	5	
Normorphine ^(B)								10	10	
Oxycodone • Thebaine								0.6	0.45	
EDDP (Primary Methadone Metabolite)										25
Phencyclidine										0.025

^(A) A blank space indicates that no cross-reactivity was observed when the compound was tested to 25 µg/mL.

^(B) A blank space indicates that no cross-reactivity was observed when the compound was tested to 10 µg/mL.

^(C) A blank space indicates that no cross-reactivity was observed when the compound was tested to 5 µg/mL.

Interfering Substances – The following compounds were spiked into normal human urine and tested for interference with the QuickScreen™ Pro Multi Drug Screening Test. The compounds were tested to 100 µg/mL, except as noted, with no interference observed.

Acetaminophen • Acetoacetic Acid • Acetone • *N*-Acetylprocainamide • Acetylsalicylic Acid (Aspirin) • Albumin • Alphenal • Amantadine • (+)-Amethopterin • Amikacin • *dl*-Aminoglutethimide • Aminopyrine • Amitriptyline • Amoxicillin • Ampicillin • Apomorphine • (-)-Arteranol • *l*-Ascorbic Acid (Vitamin C) • Aspartame • *d*-Aspartic Acid • *dl*-Aspartic Acid • *l*-Aspartic Acid • Atropine • Barbituric Acid • Benzoic Acid • Benzphetamine • Benzotropine Methane Sulfonate • Bilirubin • Bromocriptine Mesylate • (+)-Brompheniramine • Caffeine • Cannabidiol • Cannabinol • Carbamazepine • Cephalixin • Chloramphenicol • Chloroquine • (+)-Chlorpheniramine • (±)-Chlorpheniramine • Chlorpromazine • Chlorpropa-mide • Chlorprothixene • Cimetidine • Clemastine • Clomipramine • Clonidine • (-)-Cotinine • Creatinine • Cyclizine • Cyclobenzaprine • Cyclosporin A • Cyproheptadine • Desipramine • Diflunisal • Digoxin • 4-Dimethylaminoantipyrine • Diphenhydramine • Diphenoxylate •

5,5-Diphenylhydantoin • Disopyramide • Doxepin • Doxylamine • (+)-*ψ*-Ephedrine • (-)-*ψ*-Ephedrine • (+)-Ephedrine • (±)-Ephedrine • (-)-Ephedrine • (±)-Epinephrine • (-)-Epinephrine • Erythromycin • Estriol • Estrone-3-Sulfate • Ethanol • Ethosuximide • Ethyl-*p*-Aminobenzoate • Ethylenediaminetetraacetic Acid • EMDP (Secondary Methadone Metabolite) • Fenfluramine • Fenpropfen • Furosemide • Gentamicin • Gentisic Acid • Glucose • *dl*-Glutethimide • Griseofulvin • Guaiacol Glyceryl Ester • Hexobarbital • Human Hemoglobin • Hydrochlorothiazide • *dl*-β-Hydroxybutyric Acid • *o*-Hydroxyhippuric Acid • 5-Hydroxyindole-3-Acetic Acid • 5-Hydroxyindole-2-Carboxylic Acid • Hydroxyzine • Ibuprofen • Imipramine • Indole-3-Acetic Acid • Indole-3-Butyric Acid • Indomethacin • (+)-Isoproterenol • (±)-Isoproter-enol • (-)-Isoproterenol • Isoxsuprine • Kanamycin • Ketamine • Ketoprofen • Labetalol • Lidocaine • Lithium Carbonate • Melanin • Meperidine • Meprobamate • Mescaline • *dl*-Metanephrine • Methaqualone • (S)-6-Methoxy-α-Methyl-2-Naphthaleneacetic Acid • 2-Methyl-3-(3,4-Dihydroxyphenyl)-*dl*-Alanine • 2-Methyl-3-(3,4-Dihydroxyphenyl)-*l*-Alanine • Methylphenidate • Methpyrrolon • (±)-Metoprolol • Nafcilin • Naphazoline • α-Naphthaleneacetic Acid • β-Naphthaleneacetic Acid • Naproxen • Netilmicin • Niacinamide • Nialamide • Nialamide • Nicotinic Acid • Nifedipine • Nomifensine • Nordoxepin^(D) • Norethindrone • Nortriptyline • Noscapine • Orphenadrine • Oxalic Acid • Oxymetazoline • Papaverine • Penicillin G • Pentazocine • Phenelzine • Pheniramine • Phenothiazine • Phentermine • Phenylacetone • *l*-Phenylalanine • Phenylbutazone • *trans*-2-Phenylcyclopropylamine • *l*-Phenylephrine • (±)-Phenylpropanolamine • Piroxicam • Potassium Chloride • Prednisolone • Primidone • Procainamide • Prochlorperazine • Promazine • Promethazine • (+)-Propoxyphene • 2-Propyl-pentanoic Acid • Protriptyline • Quinidine • Quinine • Ranitidine • Riboflavin • Salicylic Acid • (-)-Scopolamine • Sodium Chloride • Sulindac • Terbutaline • Tetracycline • Tetraethylammonium Disulfide (Antabuse) • Tetrahydrozoline • Theophylline • Thioridazine • *cis*-Thiothixane • Tobramycin • Triamterene • Trifluoperazine • Triflupromazine • *dl*-Trihexyphenidyl • Trimethobenzamide • Trimethoprim • Trimipramine • Triprolidine • Urea • Uric Acid • Vancomycin • (±)-Verapamil • Zomepirac

^(D) No interference was observed when the compound was tested to 10 µg/mL.

^(E) No interference was observed when the compound was tested to 2.5 µg/mL.

Bibliography & Suggested References

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