QuickScreen™ Pro Multi Drug Screening Test
Catalog # 9233T

Test Instructions

Intended Use

The QuickScreen™ Pro 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 1000 ng/mL, Cocaine metabolite (Benzoylecgonine) at 300 ng/mL, THC metabolite (THCA) at 50 ng/mL, Opiates at 2000 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 sedative/hypnotic, anti-anxiety, 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/hypnotic 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 (Dalmane®) 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 1000) 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 (THC) 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 Benzoylecgonine. Very low concentrations of Cocaine may be detected in urine during the initial several hours, but Benzoylecgonine persists in urine at detectable concentrations for 48 hours.

Δ⁹-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-Δ⁹-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 (OPI 2000) 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 Codeine, Morphine and Thebaine. Synthetic opiates include Heroin, Hydrocodone and Levorphanol.

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 sufflation 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™ Pro 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, the absorbent end of the test device is inserted into the urine sample. The urine is absorbed into the device 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.

When sample drug levels are at or above the target cutoff, the free drug in the sample binds to the antibody / dye conjugate, preventing the antibody / dye conjugate from binding to the drug / protein con-
jugate 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, demonstrating antibody recognition and reactivity as well as confirming that the test is complete.

**Reagents & Materials Supplied**

1. 25 Self-Timed Test Devices (Cat. # 9233T); separate panels for each target drug contain:
   a. Monoclonal anti-drug antibody / colloidal gold conjugate in a protein matrix containing 0.1% sodium azide coated in the sample path
   b. Drug derivative / protein conjugate immobilized as a line in the Test Region (T)
   c. Goat anti-mouse antibody immobilized as a line in the Control Region (C)

2. Directional Insert (Cat. # 9233T-DI)

3. *(Optional)* Single Specimen Collection Kit (Cat. # 9501 or equivalent) – or –

4. *(Optional)* Split Specimen Collection Kit (Cat. # 9502 or equivalent)

**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 is established using urine only. No other fluid has 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 $\frac{1}{2}$-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 $\frac{1}{2}$-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 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 membranes.
2. Insert the reactive end 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.
3. Leave the test device in the sample cup until you are ready to read the test results.

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

**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 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 may be positive. 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

1. 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).

2. This test has been developed for testing urine samples only. Its performance using other specimens has not been substantiated.

3. 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.

4. 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.

5. This test is a qualitative screening assay. It is not designed to determine the quantitative concentration of target drugs or the level of intoxication.

6. Because QuickScreen™ is a competitive assay no prozone effect is present.

7. Occasionally, samples containing target drugs below the target drug’s cutoff sensitivity for the test may produce a positive result.

8. Point-of-care testing data is not currently available.
Performance Characteristics

Cross-Contamination – The QuickScreen™ Pro Multi Drug Screening Test was tested to ensure that the individual test panels, when assembled in the multi-panel device, had no effect on expected results. Urine samples were selected which had no target drugs present. These samples were aliquoted and spiked with target drugs / metabolites in varied combinations at 125% of the target drug cutoffs. All samples were coded and assayed in a blind study by 2 laboratory technicians using 3 lots of QuickScreen. The QuickScreen Pro Multi Drug Screening Test gave 100% correct results for all samples tested. No false results due to crossover or interaction between individual test panels were observed.

<table>
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<tr>
<th>Sample / Panel</th>
<th>BAR</th>
<th>BZD</th>
<th>MTD</th>
<th>AMP</th>
<th>MET</th>
<th>COC</th>
<th>THC</th>
<th>OPI</th>
<th>PCP</th>
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Note: Remaining performance characteristics were determined using the strip versions of the individual test panels.

Kit Comparison – The performance of the QuickScreen™ Pro Multi Drug Test was evaluated on clinical urine samples and compared with a commercially available assay at the stated cutoff concentrations for relative sensitivity and specificity and for overall agreement. Results from in-house studies and combined studies of 2 independent clinical laboratories are reported, comparing QuickScreen results with the EMIT instrument-based immunoassay.

### In-House Study Data - % Agreement

<table>
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<tr>
<th>Target Drug</th>
<th>BAR</th>
<th>BZD</th>
<th>MTD</th>
<th>AMP</th>
<th>MET</th>
<th>COC</th>
<th>OPI</th>
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<tr>
<td><strong>n =</strong></td>
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<td>180</td>
<td>109</td>
<td>189</td>
<td>189</td>
<td>164</td>
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<tr>
<td>Relative Sensitivity</td>
<td>&gt;99</td>
<td>&gt;99</td>
<td>&gt;99</td>
<td>97.6</td>
<td>95.9</td>
<td>&gt;99</td>
<td>&gt;99</td>
<td>&gt;99</td>
<td>99</td>
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<td>Overall Agreement</td>
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<td>97.3</td>
<td>98.1</td>
<td>&gt;99</td>
<td>&gt;99</td>
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### Clinical Study Data - % Agreement

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<th>AMP</th>
<th>MET</th>
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<tr>
<td><strong>n =</strong></td>
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<td>Relative Sensitivity</td>
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<td>&gt;99</td>
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<td>97.7</td>
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<tr>
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<td>96.9</td>
<td>94.1</td>
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<td>98.4</td>
<td>96.5</td>
<td>&gt;98</td>
<td>&gt;99</td>
<td>97.9</td>
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</table>

[1] 2 samples at 324 and 336 ng/mL (8% and 12% above cutoff, respectively) gave negative results in the Methadone Clinical Study.

[2] 5 discrepant results were observed in the Cocaine Clinical Study; the samples were from 3 – 10% below the assay cutoff concentration (271 to 293 ng/mL) and subsequently tested positive by GC/MS.
**Precision** – Eight urine pools ranging in concentration from 0 to 200% of cutoff were assayed twice a day for 20 days. Results were interpreted individually by 2 technicians. The precision of the Quick-Screen™ Pro Test was determined to be >95% for all assays.

**Cross-Reactive Substances** – The following compounds were spiked into normal human urine and tested for cross-reactivity with the QuickScreen™ Pro Multi Drug Screening Test. The results (in $\mu$g/mL) are expressed as that amount of compound capable of giving a result equivalent to the target drug at its cutoff concentration. Except where noted, a blank space indicates that no cross-reactivity was observed when the compound was tested to 100 $\mu$g/mL.

<table>
<thead>
<tr>
<th>Compound</th>
<th>BAR</th>
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<td>Barbital • Butabarbital • Pentobarbital</td>
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<td>5,5-Diallylbarbituric Acid</td>
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<td>(±)-Thiopental</td>
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<td>Desmethyl Diazepam</td>
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<tr>
<td>Diazepam • Flunitrazepam</td>
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<td>(−)−α-Acetylmethadol (LAAM)</td>
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Cross-Reactive Substances, continued

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<th>MET</th>
<th>COC</th>
<th>THC</th>
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<td>Benzoylecgonine • Cocaine</td>
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<td>Metoclopramide</td>
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<td>11-Hydroxy-Δ⁹-THC[(C)]</td>
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<td>Morphine-3β-D-Glucuronide</td>
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<td>EDDP (Primary Methadone Metabolite)</td>
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[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 where noted, with no interference noted.

- Acetaminophen
- Acetoacetic Acid
- Acetone
- N-Acetylprocainamide
- Acetylsalicylic Acid (Aspirin)
- Albumin
- Alphenal
- Amantadine
- (+)-Amethopterin
- Amikacin
- dl-Aminoglutethimide
- Aminopyrine
- Amitriptyline
- Amoxicillin
- Ampicillin
- Apomorphine
- (-)-Arterenol
- l-Ascorbic Acid (Vitamin C)
- Aspartame
- d-Aspartic Acid
- dl-Aspartic Acid
- l-Aspartic Acid
- Atropine
- Barbituric Acid
- Benzoic Acid
- Benzphetamine
- Benztpine Methane Sulfonate
- Bilirubin
- Bromocriptine Metylate
- (+)-Brompheniramine
- Caffeine
- Cannabidiol
- Cannabinol
- Carbamazepine
- Cephalexin
- Chloramphenicol
- Chloroquine
- (+)-Chlorpheniramine
- (±)-Chlorpheniramine
- Chlorpromazine
- Chlorpropamide
- Chlorprothixene
- Cimetidine
- Clemastine
- Clomipramine
- Clonidine
- (-)-Cotinine
- Creatinine
- Cyclophosphamide
- Cyclopentazine
- Cyclosporin A
- Cyproheptadine
- Desipramine
- Dextromethorphan
- Diflunisal
- Digoxin
- 4-Dimethylaminopyridine
- Diphenhydramine
- Diphenoxylate
- 5,5-Di-phenylhydantoin
- 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
- Fenoprofen
- Fentanyl[B]
- Furosemide
- Gentamicin
- Gentisic Acid
- Glucose
- dl-Glutethimide
- Griseofulvin
- Guaiacol Glycerol
- 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
- (±)-Isoproterenol
- (−)-Isoproterenol
- Isoxsuprime
- Kanamycin
- Ketamine
- Ketoprofen
- Labetalol
- Levorphanol
- Lidocaine
Interfering Substances, continued

- Lithium Carbonate  
- Lysergic Acid Diethylamide (LSD)[E]  
- Melanin  
- Meperidine  
- Meprobamate  
- Mescaline  
- dl-Methanephrine  
- Methaqualone  
- (S)-6-Methoxy-α-Methyl-2-Naphthaleneacetic Acid  
- 2-Methyl-3-(3,4-Dihydroxyphenyl)-dl-Alanine  
- Methylphenidate  
- Methyprylon  
- (±)-Metoprolol  
- Nafcilin  
- Naloxone  
- Naltrexone  
- Naphazoline  
- α-Naphthaleneacetic Acid  
- β-Naphthaleneacetic Acid  
- Naproxen  
- Netilmicin  
- Nicotinamide  
- Nicotinic Acid  
- Nifedipine  
- Nomifensine  
- Norethindrone  
- Normorphine[B]  
- Nortriptyline  
- Noscapine  
- Orphenadrine  
- Oxalic Acid  
- Oxycodone  
- Oxymetazoline  
- Papaverine  
- Penicillin G  
- Pentazocine  
- Phenelzine  
- Phenothiazine  
- Phentermine  
- Phenylacetone  
- l-Phenylalanine  
- Phenylbutazone  
- trans-2-Phenylcyclopropylamine  
- l-Phenylephrine  
- (±)-Phenylpropanolamine  
- Piroxicam  
- Potassium Chloride  
- Prednisolone  
- Procainamide  
- Prochlorperazine  
- Promazine  
- Promethazine  
- (+)-Propoxyphene  
- 2-Propylpentanoic Acid  
- Protriptyline  
- Quinidine  
- Quinol  
- Ranitidine  
- Riboflavin  
- Salicylic Acid  
- (−)-Scopolamine  
- Sodium Chloride  
- Sulindac  
- Terbutaline  
- Tetracycline  
- Tetraethylthiuram Disulfide (Antabuse)  
- Tetrhydrozoline  
- Thebaine  
- Theophylline  
- Thoridazine  
- cis-Thiothixene  
- Tobramycin  
- Triamterene  
- Trifluoperazine  
- Triflupromazine  
- dl-Trihexyphenidyl  
- Trimethobenzamide  
- Trimethoprim  
- 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.

Endogenous Conditions – Urine conditions of pH, ranging from 4.5 to 8.5, and specific gravity, ranging from 1.005 to 1.040, were tested in normal human urine with the QuickScreen™ Pro test and found to have no effect on expected results.

Bibliography & Suggested References


QuickScreen™ Pro Multi Drug Screening Test
Catalog # 9233T-25
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Tel: (858) 635-5840 / Fax: (858) 635-5843 / Website: www.phamatech.com
9233T-DI, Doc. # 100720, Rev. A, Eff. 12/15/00