Quick Screen Cocaine Test (RAP-2839)

INTENDED USE

The QuickScreen One Step Cocaine Screening Test is a rapid, qualitative immunoassay for the detection of Benzoylecgonine, a hydrolytic degradation product, in urine. The cutoff concentration for this test is 300 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 confirmation methods are available. Clinical consideration and professional judgement should be applied to any drug-of-abuse test results, certainly when preliminary positive results are observed.

SUMMARY AND EXPLANATION

Cocaine is an alkaloid present in coca leaves (Eryrthroxine coca) whose pharmacological properties include alertness, wakefulness, increased energy and an overall feeling of euphoria[6]. Cocaine has been used medicinally as a local anesthetic, however its addictive properties have minimized its modern value as an anesthetic[5]. Elimination of cocaine is predominantly controlled by its biotransformation. 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 hrs. 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 specimens.

PRINCIPLES OF THE PROCEDURE

QuickScreen™ One Step Cocaine Screening Test is a competitive immunoassay that is used to screen for the presence of Benzoylecgonine in urine. It is a chromatographic absorbent device in which drug or drug metabolites in a sample compete with drug conjugate immobilized on a porous membrane for a limited number of binding sites. The test device employs a unique combination of monoclonal and polyclonal antibodies to selectively identify Benzoylecgonine in urine with a high degree of confidence. In the assay procedure, urine is added to the test device in the Sample Well with a plastic transfer pipette. Urine is absorbed into the device by capillary action, mixes with the antibody/dye conjugate and flows across the coated membrane. When Benzoylecgonine levels are below 300 ng/ml (the detection sensitivity of the test), antibody/dye conjugate binds to free drug/protein conjugate immobilized in the Testregion (T) of the device. This produces the development of a distinct color band that regardless of its intensity indicates a negative result. When Benoylecgonine levels are at or above 300 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 color 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 AND MATERIALS PROVIDED

1. **50 Test Devices containing:**
   - **a)** Monoclonal anti-Benzoylecgonine antibody/colloidal gold-conjugate in a protein matrix containing 0.1% sodium azide bound to a membrane. As control, mouse IgG-colloidal gold is coated in the sample path.
   - **b)** Benzoylecgonine/protein conjugate immobilized as a line in the test region.
   - **c)** Coat anti-mouse antibody immobilized as a line in the control region.
2. **Directional Insert**

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

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. 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, unused and without preservatives. The container should not have been used previously or contain preservatives. Testing requires only a small volume (1to 2 ml) of urine in the sample container.

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, remove the test device, and place it on a clean, level surface.
2. Hold the dropper 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 results immediately at (10) minutes. Results read after 15 minutes should be considered invalid.

INTERPRETATION OF THE 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). This result indicates that is below the detection sensitivity of 300 ng/ml.

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 Benzoylecgonine level that is at or above the detection sensitivity of 300 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, using 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 in the Control Region (C), and no band 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. 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 drugs or the level of intoxication.
7. Because the QuickScreen is a competitive assay, no prozone effect is present.
8. Occasionally, samples containing target drug concentrations below the cut-off sensitivity for the test may produce a positive result.

PERFORMANCE CHARACTERISTICS

Sensitivity – The QuickScreen™ Cocaine Screening Test detects the cocaine metabolite Benzoylecgonine at a cutoff concentration equla to or greter than 300 ng/ml. The sensitivity of the The QuickScreen™ Cocaine Screening Test was evaluated on 164 urine samples and compared with both commercially available immunoassays and GC/MS. Using the 200-ng/ml cutoff, an agreement of greater than 99% was observed.

Specificity – In three separate laboratory studies, including two clinical trials, a specificity of treater than 98% (111/113) was observed when compared to a commercially available test.

Accuracy – The accuracy of the The QuickScreen™ Cocaine Screening Test was evaluated on 164 urine samples and compared to a commercially available immunoassay using the cutoff concentrations stated above. An agreement of greater than 99% was observed. In addition, studies at two independent clinical laboratories produced an agreement of 96.5% (276/286) accuracy when compared to the EMIT II assay.

Precision – Eight urine pools ranging from 0 to 568 ng/ml Benzoylecgonine were assayed twice a day for 20 days. Two technicians individually interpreted the results. The inter- and intra-assay coefficients of variation were less than 1% for all samples.

Cross-Reacting Substances – The following structurally related compounds were spiked into normal human urine and found to cross-react in The QuickScreen™ Cocaine Test. The results, in ng/ml, are expressed as that amount of compund that produces a result equivalent to 300 ng/ml of Benoylecgonine.

Compound	Concentration	Compound	Concentration
Benoylecgonine	300	Pyrilamine	100,000
Cocaine	300	Metoclopramide	25,000
Procaine	100,000		

Interfering Substances – The following compounds were spiked into normal human urine and tested for interference with the QuickScreen Cocaine Test. Except as noted, the compounds were tested to a concentration of 100,000 ng/ml and found not to interfere.

Acetaminophen - Acetone – *N*-Acetylprocainamide – Acetylsalicylic Acid (Aspirin) – Albumin – Alphenal - Alprazolam[(A)] – Amantadine – (+)-Amethopterin – Amikacin – *dl*-Aminoglutethimide – Aminopyrine – Amitriptyline – 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 – Benzphetamine – Benztropine Methane Sulfonate – Bilirubin – Bromazepam, Bromocriptine Mesylate – (+)-Brompheniramine – Butabarbital – Butethal – Caffein - Cannabidiol – Cannabinol - Carbamazepine – Cephalexin – Chloramphenicol – Chlordiazepoxide – Chloroquine – (+) & (±)-Chlorpheniramine – Chlorpromazine – Chlorpropamide – Chlorprothixene – Cimetidine – Clemastine – Clomipramine – Clonazepam – Clonidine – Codeine – (-)-Cotinine – Creatinine – Cyclizine – Cyclobenzaprine – Cyclosporin A, Cyproheptadine –(-)-Deoxyephedrine - Desipramine – Desmethyldiazepam – Dextromethorphan – 5,5-Dial-lylbarbituric Acid -Diazepam – Diflunisal – Digoxin – Diphenhydramine – 4-Dimethyl-aminoantipyrine- Diphenoxylate – 5,5-Dipenylhydantoin – Disopyramide – Doxepin – Doxylamine – (+) & (-)-ψ-Ephedrine - (+),(±) & (-)-Ephedrine – (±) & (-)-Epinephrine – Erythromycin – Estriol – Estrone-3-Sulfate – Ethosuximide – Ethyl-*p*-Aminobenzoate – 2-Ethylidene-1,5-Dimethyl-3,3-Diphenylpyrrolidine (EDDP) – Ethylmorphine[B] - Fenfluramine – Fenoprofen - Fentanyl[B] - Flunitrazepam – Flurazepam – Furosemide – Gentamicin – Gentisic Acid – *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 – Ketamine – Ketoprofen – Labetalol – Levorphanol – Lidocaine – Lithium Carbonate – (±)-Lorazepam – Lormetazepam – Lysergic Acid Diethylamide[D] - Medazepam – Melanin – Meperidine – Mephentermine – Meprobamate – Mescaline – *dl*-Methaneprine – (±)-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 – Methylphenidate – Methyprylon – (±)-Metoprolol – Morphine – Morphine-3-*β*-D-Glucuronide, Nafcillin – Nalorphine – Naloxone – Naltrexone – Naphazoline - α & β-Naphthaleneacetic Acid – Naproxen - Netilmicin – Niacinamide – Nialamide – Nicotinic Acid – Nifedipine – Nitrazepam – Nomifensine – Norcodeine – Nordoxepin[B] - Norethindrone - Normorphine[B] - 11-Nor-Δ^8 & Δ^9-THC-Carboxylic Acid[C] - Nortriptyline – Noscapine – Nylidrin – Orphenadrine – Oxalic Acid – Oxazepam – Oxycodone – Oxymetazoline – Papaverine – Penicillin G – Pentazocine – Pentobarbital - Phencyclidine – Phenelzine – Pheniramine – Phenothiazine – Phentermine – Phenylacetone – *l*-Phenylalanine – Phenylbutazone – *trans*-2-Phenylcyclopropylamine – *l*-Phenylephrine – (R)-(+)-α, (±)-α & β-Phenylethylamine – (±)-Phenylpropanolamine – Piroxicam – Potassium Chloride – Prazepam – Prednisolone – Primidone – Procainamide – Procaine – Prochlorperazine – Promazine – Promethazine – (+)-Propoxyphene – 2-Propylpentanoic Acid – Protriptyline – Quinidine – Quinine – Ranitidine – Riboflavin – Salicylic Acid – (-)-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 – *dl*-Trihexyphenidyl – Trimethobenzamide – Trimethoprim – Trimipramine – Triprolidine – Tyramine – Urea – Uric Acid – Vancomycin – (±)-Verapamil – Zomepirac.

[(A)] No interference was observed when the compount was test 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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