

DRG[®] Opiates Test (RAP-2831)

Revised 24 May 2011 rm (Vers. 3.1)

IVD

Please use only the valid version of the package insert provided with the kit.

Intended Use

The QuickScreen One Step Opiates Screening Test is a rapid, qualitative immunoassay for the detection of opiates and opiate metabolites 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 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 & Explanation of the Test

Opiates 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.

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

The QuickScreen One Step Opiates Screening Test is a competitive immunoassay that is used to screen for the presence of Opiates and their metabolites 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 Opiates and their metabolites in urine with a high degree of confidence.

In the assay procedure, a urine sample is added to the test device in the Sample Well "S," where it is absorbed into the device by capillary action. The urine mixes with the antibody-dye conjugate and flows across the pre-coated membrane.

When sample Opiate levels are below 300 ng/mL (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 Opiate 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 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.

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1. 50 Test Devices containing:
 - a. Monoclonal anti-Morphine antibody / colloidal gold conjugate in a protein matrix containing 0.1% sodium azide coated in the sample path
 - b. Morphine 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
3. (Optional) Single Specimen Collection Kit (Cat. # 9501 or equivalent) – or –
4. (Optional) Split Specimen Collection Kit (Cat. # 9502 or equivalent)

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 is established using urine. No other fluid has been evaluated.
6. Do not reuse the test device.

Storage & Handling Requirements

Store at room temperature (15 °C – 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 1/2-inch (50 – 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 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.

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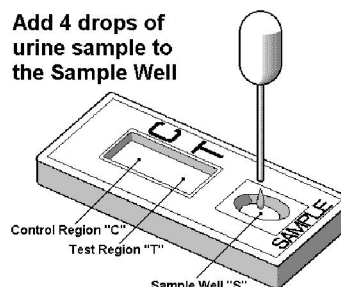
Assay Procedure

Preparation

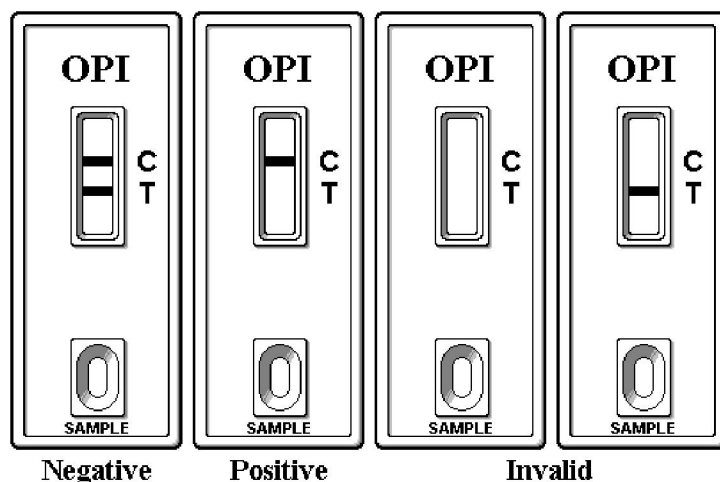
1. Confirm that all samples and test components are at room temperature (15 – 28 °C) before testing.
2. Do not break the seal on the foil pouch until you are ready to perform the test.

Testing

1. Open the foil pouch at the notch and remove the test device and transfer pipette.
Take care not to touch the exposed membrane. Place the device on a clean, level surface.
2. Hold the dropper vertically and dispense four (4) full drops of urine into the Sample Well.
Wait five (5) seconds between adding each drop.
3. Read the result immediately at ten (10) minutes.
Results read after more than 10 minutes have elapsed should be considered invalid.



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). This result indicates an Opiate level that is below the detection sensitivity of 300 ng/mL.

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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 an Opiate 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, 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. 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. Strong oxidizing agents such as bleach (hypochlorite) can oxidize drug analytes. If a sample is suspected of being adulterated, obtain a new sample.
4. 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.
5. This test is a qualitative, competitive screening assay. It is not designed to determine the quantitative concentration of Opiates or the level of intoxication.
6. Because the QuickScreen Test is a competitive assay, no prozone effect is present.
7. Occasionally, samples containing Opiate levels below the cutoff sensitivity for the test may produce a positive result.

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Performance Characteristics

Sensitivity

The QuickScreen Opiate Screening Test detects opiate or opiate metabolite at a cutoff concentration of 300 ng/mL. The sensitivity of the QuickScreen™ Test was evaluated on 116 urine samples and compared with both commercially available immunoassays and GC/MS. At greater than or equal to 300 ng/mL, an agreement of 98% was observed.

Specificity

In three separate laboratory studies, including 2 clinical trials, a specificity of >99% (95/95) was observed when compared to two commercially available opiate tests.

Accuracy

The accuracy of the QuickScreen Opiate Screening Test was evaluated on 176 urine samples and compared with two commercially available immunoassays using the 300 ng/mL cutoff. An agreement of >99% was observed. In addition, studies at 2 separate, independent clinical laboratories produced an agreement of >99% (151/151) when compared to the Emit II assay.

Cross-Reactivity

The following structurally related compounds were spiked into normal human urine and found to cross-react in the QuickScreen Opiates Test. The results, in ng/mL, are expressed as that amount of compound capable of giving a result equivalent to 300 ng/mL of Morphine.

Compound	Conc.	Compound	Conc.
Codeine	300	Morphine-3β-D-Glucuronide	300
Dextromethorphan	50,000	Nalorphine	500
Ethylmorphine	350	Naloxone	400
Heroin	300	Naltrexone	5,000
Hydrocodone	400	Norcodeine	500
Hydromorphone	400	Normorphine	10,000
Levorphanol	500	Oxycodone	600
Morphine	300	Thebaine	600

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Interfering Substances

The following compounds were spiked into normal human urine and tested for interference with the QuickScreen Opiates Test. These compounds were tested to 100 µg/mL, unless otherwise noted, with no interference observed.

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 • Barbitol • Barbituric Acid • Benzoic Acid • Benzoyllecgonine • Benzphetamine • Benztropine Methane Sulfonate • Bilirubin • Bromazepam • Bromocriptine Mesylate • (+)-Brompheniramine • Butabarbital • Butalbital • Butethal • Caffeine • Cannabidiol • Cannabinol • Carbamazepine • Cephalexin • Chloramphenicol • Chlordiazepoxide • Chloroquine • (+) & (±)-Chlorpheniramine • Chlorpromazine • Chlorpropamide • Chlorprothixene • Cimetidine • Clemastine • Clomipramine • Clonazepam • Clonidine • Cocaine • (–)-Cotinine • Creatinine • Cyclizine • Cyclobenzaprine • Cyclosporin A • Cyproheptadine • (–)-Deoxyephedrine • Desipramine • Desmethyldiazepam • 5,5-Diallylbarbituric Acid • Diazepam • Diflunisal • Digoxin • 4-Dimethylaminoantipyrine • Diphenhydramine • Diphenoxylate • 5,5-Diphenylhydantoin • Disopyramide • Doxepin • Doxylamine • (+)-*ψ* & (–)-*ψ*-Ephedrine • (+), (±) & (–)-Ephedrine • (±) & (–)-Epinephrine • Erythromycin • Estriol • Estrone-3-Sulfate • Ethanol • Ethosuximide • Ethyl-*p*-Aminobenzoate • 2-Ethylidene-1,5-Dimethyl-3,3-Diphenylpyrrolidine (EDDP) • Fenfluramine • Fenpropfen • Fentanyl^[B] • Flunitrazepam • Flurazepam • Furosemide • Gentamicin • Gentisic Acid • Glucose • *dl*--Glutethimide • Griseofulvin • Guaiacol Glyceryl Ester • Hemoglobin, Human • Hexobarbital • Hydrochlorothiazide • *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 • Lidocaine • Lithium Carbonate • (±)-Lorazepam • Lormetazepam • Lysergic Acid Diethylamide (LSD)^[D] • Medazepam • Melanin • Meperidine • Mephentermine • Meproamate • Mescaline • *dl*-Metanephine • (±)-Methadone • (+)-Methamphetamine • Methaqualone • (S)-6-Methoxy- α -Methyl-2-Naphthaleneacetic Acid • 2-Methyl-3-(3,4-Dihydroxyphenyl)-*dl* & *l*-Alanine • (±)-3,4-Methylenedioxymphetamine • (±)-3,4-Methylenedioxymethamphetamine • Methylphenidate • Methypylon • Metoclopramide • (±)-Metoprolol • Nafcillin • Naphazoline • α & β -Naphthaleneacetic Acid • Naproxen • Netilmicin • Niacinamide • Nialamide • Nicotinic Acid • Nifedipine • Nitrazepam • Nomifensine • Nordoxepin^[B] • Norethindrone • 11-Nor- Δ^8 & Δ^9 -THC-Carboxylic Acid^[C] • Nortriptyline • Noscapine • Nylidrin • Orphenadrine • Oxalic Acid • Oxazepam • Oxymetazoline • Papaverine • Penicillin G • Pentazocine • Pentobarbital • Phencyclidine • Phenelzine • Pheniramine • Phenobarbital • 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 • Pyrilamine • Quinidine • Quinine • Ranitidine • Riboflavin • (–)-Scopolamine • Secobarbital • Sodium Chloride • Sulindac • Temazepam • Terbutaline • Tetracycline • Tetraethylthiuram Disulfide • Δ^8 & Δ^9 -Tetrahydrocannabinol • Tetrahydrozoline • Theophylline • Thioridazine • *cis*-Thiothixene • Tobramycin • Triamterene • Triazolam^[B] • Trifluoperazine • Trifluoromazine • *dl*-

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Trihexyphenidyl • Trimethobenzamide • Trimethoprim • Trimipramine • Triprolidine • Tyramine • Urea •
Uric Acid • Vancomycin • (±)-Verapamil • Zomepirac

- [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.

Bibliography & Suggested References

1. Federal Register, Department of Health and Human Services, Mandatory Guidelines for Federal Workplace Drug Testing Programs 53 (69) 1988
2. Urine Testing for Drugs of Abuse, NIDA Research Monograph 73, (1986)
3. Dasgupta A., Saldana S., Kinnaman G., Smith M., Johansen K., Clinical Chemistry, 39:104-108 (1993)
4. Liu R.H., Goldberger B.A., Handbook of Workplace Drug Testing, AACCC Press (1995)
5. Jeffcoat A.R., et al, Drug Metabolism and Disposition, 17-2 (1989)
6. Inaba T., Journal of Canadian Physiology and Pharmacology, 67:1154-1157 (1989)
7. Karch S.B., Drug Abuse Handbook, CRC Press (1998)

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