QuickScreen™ THC Test Dipstick Rapid Test (RAP-2840)

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Revised 10 Sept. 2010 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 THC Test is a rapid, qualitative immunoassay for the detection of the THC metabolite (THCA) and other cannabinoid compounds in urine.
The cutoff for this test is 50 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 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 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

Δ^9-Tetrahydrocannabinol (THC) is generally accepted to be the principle active component in marijuana, although other cannabinoids are likely to contribute to the physiological activity of marijuana. Tetrahydrocannabinol is rapidly absorbed by inhalation and the gastrointestinal tract. It is almost completely metabolized. The predominant metabolite, 11-Nor-Δ^9-THC-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, but THCA persists in urine at a detectable concentration for many days after smoking.
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.

Principles of the Procedure

The QuickScreen One Step THC Test is a competitive immunoassay that is used to screen for the presence of THCA 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 THCA and other cannabinoid compounds in urine with a high degree of confidence.
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 THCA levels are below 50 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 THCA levels are at or above 50 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 demostrating antibody recognition and reactivity as well as confirming that the test is complete.

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Reagents and Materials Supplied

1. 25 or 50 Test Devices containing:
   a. Monoclonal anti-THCA antibody / colloidal gold conjugate in a protein matrix containing 0.1% sodium azide coated in the sample path
   b. THCA 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 # on request) – or –
4. (Optional) Split Specimen Collection Kit (Cat # on request)

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

Warnings and 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.

Storage and Handling RequirementS

Store at room temperature (15-28°C); do not freeze. See expiration date for stability.

Sample Collection and 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 Quick-Screen 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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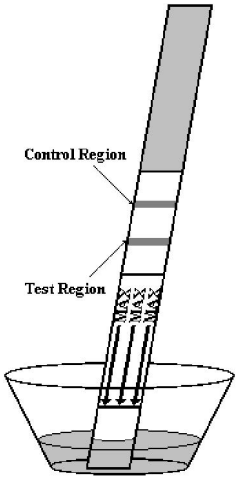
Assay Procedure

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. Take care not to touch the exposed membrane.
2. Insert the reactive end of the device into the urine sample. DO NOT immerse the device any deeper into the sample than the maximum level indicated by the line on the device label.
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

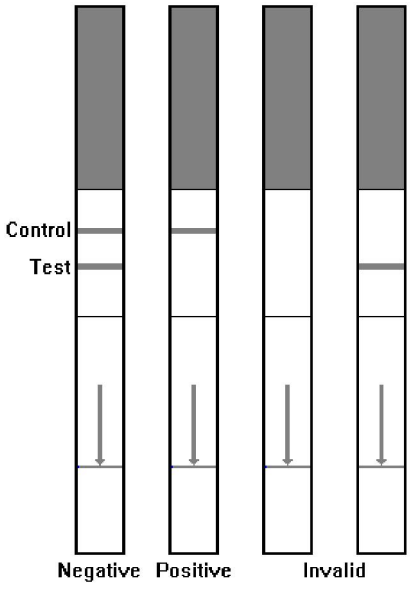
A negative result is indicated when two (**2**) colored bands appear, one in the Control Region (**C**) and one in the Test Region (**T**).
This result indicates a THCA level that is below the detection sensitivity of 50 ng/mL.

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 THCA level that is at or above the detection sensitivity of 50 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.



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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. A 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 THC or the level of intoxication.
6. Because it is a competitive assay, no prozone effect is present.
7. Occasionally, samples containing THC levels below the cut-off sensitivity for the test may produce a positive result.

Performance Characteristics

Sensitivity

The QuickScreen THC Screening Test detects 11-Nor-Δ^9-tetrahydrocannabinol-2-carboxylic acid at a cutoff concentration of 50 ng/mL. The sensitivity of the QuickScreen THC screening Test was evaluated on 143 urine samples and compared with a commercially available immunoassay. Using the cutoff concentration stated above, an agreement of > 99% was observed. In addition, two clinical laboratories reported a combined sensitivity of 98% (100/102) when comparing QuickScreen to a commercially available (EMITII) instrument-based immunoassay.

Specificity

In 3 separate laboratory studies, including 2 clinical trials, a specificity of > 99% (99/99) was observed when compared to commercially available THC tests.

Accuracy

The accuracy of the QuickScreen THC Screening Test was evaluated on 143 GC/MS-confirmed urine samples and compared with a commercially available immunoassay uring a 50 ng/mL cutoff. An agreement of > 99% (143/143) was observed. In addition, studies at two separate, independent clinical laboratories produced an agreement of > 98% (135/137) when compared to the EMITII assay.

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Precision

Eight GC/MS-confirmed urine pools ranging from 0 to 96 ng/mL were assayed twice a day for twenty days with the QuickScreen THC Screening Test. The results were individually interpreted by two technicians. The inter- and intra-assay coefficients of variation were < 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 THC Test. The results, in ng/mL, are expressed as that amount of compound that produces a result equivalent to 50 ng/mL of 11-NorΔ^9-THC-2-carboxylic Acid.

Compound	Conc.
11-Hydroxy-Δ^9-THC	1,000
11-Nor-Δ^8-THC-2-Carboxylic Acid	100
11-Nor-Δ^9-THC-2-Carboxylic Acid	50
Δ^8-Tetrahydrocannabinol	100,000
Δ^9-Tetrahydrocannabinol	50

Interfering Substances

Interfering Substances – The following compounds were spiked into normal human urine and tested with the QuickScreen™ THC Test. The compounds were tested to a concentration of 100 µg/mL, except where noted, and no interference was 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 • Aspartame • *d*, *dl* & *l*-Aspartic Acid • Atropine • Barbital • Barbituric Acid • Benzoic Acid • Benzoylecgonine • Benzphetamine • Benztropine Methane Sulfonate • Bilirubin • Bromazepam • Bromocriptine Mesylate • (+)-Brom-pheniramine • Butabarbital • Butalbital • Butethal • Caffeine • Cannabidiol • Cannabinol • Carbamazepine • Cephalexin • Chloramphenicol • Chlordiazepoxide • Chloroquine • (+) & (±)-Chlorpheniramine • Chlorpromazine • Chlorpropamide • Chlorprothixene • Cimetidine • Clemastine • Clomipramine • Clonazepam • Clonidine • Cocaine • Codeine • (–)-Cotinine • Creatinine • Cyclizine • Cyclobenzaprine • Cyclosporin A • Cyproheptadine • (–)-Deoxyephedrine • Desipramine • Desmethyldiazepam • Dextromethorphan • 5,5-Diallylbarbituric Acid • Diazepam • Diflunisal • Digoxin • 4-Dimethylaminoantipyrine • Diphenhydramine • Diphenoxylate • 5,5-Di-phenylhydantoin • Disopyramide • Doxepin • Doxylamine • (+) & (–)-ψ-Ephedrine • (+), (±) & (–)-Ephedrine • (±) & (–)-Epinephrine • Erythromycin • Estriol • Estrone-3-Sul-fate • Ethanol • 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 • Glucose • *dl*-Glutethimide • Griseofulvin • Guaiacol Glyceryl Ester • Hemoglobin, Human • Heroin[B] • Hexobarbital • Hydrochlorothiazide • Hydrocodone • Hydromorphone • *o*-Hydroxyhippuric Acid • 5-Hydroxyindole-3-Acetic Acid • 5-Hydroxyin-dole-2-Carboxylic Acid • 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 (LSD)[C] • Medazepam • Melanin • Meperidine • Mephentermine • Meprobamate • Mescaline • *dl*-Metane-phrine • (±)-Methadone • (+)-Methamphetamine • Methaqualone • (S)-6-Methoxy-α-Methyl-2-Naphthaleneacetic Acid • 2-Methyl-3-(3,4-Dihydroxyphenyl)-*dl* & *l*-Alanine • (±)-3,4-Methylenedi-oxyamphetamine • (±)-3,4-Methylenedioxymethamphetamine • Methylphenidate • Methyprylon • Metoclopramide • (±)-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] • Nortriptyline • Noscapine • Nylidrin • Orphenadrine • Oxalic Acid • Oxazepam • Oxycodone • 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 (Antabuse) • Tetrahydrozoline • Thebaine • Theophylline • Thioridazine • *cis*-Thiothixene • Tobramycin • Triamterene • Triazolam[B] • Trifluoperazine • Triflupromazine • *dl*-Trihexyphenidyl •

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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 2.5 µg/mL.

Bibiliography and Suggested References

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