

Quick Screen THC Test (RAP-2841)**INTENDED USE**

The QuickScreen One Step THC Screening test is a rapid, qualitative immunoassay for detection of Tetrahydrocannabinol and other cannabinoid compounds in urine. The cutoff concentration 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 use in clinical toxicology laboratories, physician's offices, drug-of-abuse clinics and law enforcement agencies.

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

Tetrahydrocannabinol (THC) is generally accepted to be the principle active component in marijuana. Inhalation and the gastrointestinal tract rapidly absorb tetrahydrocannabinol. 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 drug 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 THC in urine. It is a chromatographic absorbent device in which drug 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 THC 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 with the aid of a plastic transfer pipette. The urine 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 THC levels are below 50 ng/ml (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 THC levels are at or above 50 ng/ml, the free drug in the sample binds to the antibody/Dye conjugate immobilized in the Test Region (T) of the device. This prevents the development of a distinct colored band. This indicates a potentially positive sample. In either case, a colored band 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 & MATERIALS SUPPLIED

1. 25 Test Devices:
 - a) The test device contains mouse monoclonal anti-THCA/colloidal gold conjugate in a protein matrix containing 0.1% sodium azide coated in the sample path
 - b) THCS derivate/protein conjugate immobilized as a line in the test region
 - c) Goat anti-mouse antibody immobilized as a line in the control region
2. Directional Insert

MATERIALS REQUIRED BUT NOT SUPPLIED

1. Clock or other suitable timer.
2. Sample collection containers.

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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 only. Other fluids have not been evaluated.
6. Do not reuse the Test Device.

STORAGE AND HANDLING REQUIREMENT

This kit is to be stored 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. Testing requires at least 1/2-inch (50 to 60 ml) of urine in the sample container. If required by your procedure aliquot a portion of urine into a second 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 to 8° C. For longer storage, freeze samples at -20° C or below.

ASSAY PROCEDURE

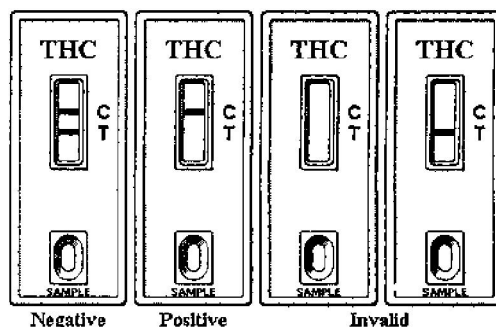
PREPARATION

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 4 full drops of urine into the Sample Well of the test device. Wait 5 seconds between adding each drop.
3. Read the results immediately at (10) minutes.
4. Attention: Results read after 15 minutes have elapsed and should be considered invalid.

Interpretation of Test Results



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INTERPRETATION OF TEST RESULTS

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 THC level that is at or above the detection sensitivity of 50 ng/ml.

Negative: A Negative result is indicated by two (2) colored bands appear, one in the control region (C) and one in the test region (T). This result indicates a THC level that is below 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.

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 should 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 Test Region (T) and one in the Control Region (C).

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, a new sample must be obtained.
5. All positive samples must be confirmed by another method. GC/MS is the method of choice to confirm the presence and concentration of drug urine.
6. This test is a qualitative, competitive screening assay. It is not designed to determine the quantitative concentration of THC or the level of intoxication.
7. Because it is a competitive assay, no prozone effect is present.
8. 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 Tests detects 11-Nor- Δ^9 -tetrahydrocannabinol-9-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 greater than 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 three separate laboratory studies, including 2 clinical trials, a specificity of greater than 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 urine samples and compared with a commercially available immunoassay using a 50 ng/ml cutoff. An agreement of >99% (143/143) was observed. In

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addition, studies at two separate, independent clinical laboratories produced an agreement of greater than 98% (135/137) when compared to the EMITII assay. All sample concentrations were confirmed by GC/MS analysis.

PRECISION

Eight urine pools ranging from 0 to 96 ng/ml (confirmed by GC/MS analysis) were assayed twice a day for twenty days with the QuickScreen THC Screening Test. Two technicians individually interpreted the results. The inter- and intraassay coefficients of variation were less than 1% for all samples. All sample concentrations were.

CROSS-REACTING AND INTERFERING 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-nor Δ^9 -THC-9-carboxylic Acid.

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

INTERFERING SUBSTANCES

The following compounds were spiked into normal human urine and tested for interference with the QuickScreen Barbiturates Test. Unless noted, these compounds were tested to 100 μ g/ml 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 – Benzoylcegonine – Benzphetamine – Benztropine Methane Sulfonate – Bilirubin – Bromazepam, Bromocriptine Mesylate – (+)-Brompheniramine – Butalbital – Butethal – Caffeine – Cannabidiol – Cannabinol – Carbamazepine – Cephalixin – Chloramphenicol – Chlordiazepoxide – Chloroquine – (+) & (\pm)-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 – Diphenhydramine – 4-Dimethyl-aminoantipyrine – Diphenoxylate – 5,5-Diphenylhydantoin – Disopyramide – Doxepin – Doxylamine – (+) & (-)- ψ -Ephedrine – (+), (\pm) & (-)-Ephedrine – (\pm) & (-)-Epinephrine – Erythromycin – Estril – Estrone-3-Sulfate – Ethanol – Ethosuximide – Ethyl-*p*-Aminobenzoate – 2-Ethylidene-1,5-Dimethyl-3,3-Diphenylpyrrolidine (EDDP) – Ethylmorphine^[B] – Fenfluramine – Fenpropfen – Fentanyl^[B] – Flunitrazepam – Flurazepam – Furosemide – Gentamicin – Gentisic Acid – *dl*-Glutethimide – Griseofulvin – Guaiacol Glyceryl Ester – Hemoglobin Human – Heroin^[B] – Hexobarbital – Hydrochlorothiazide – Hydrocodone – Hydromorphone – *o*-Hydroxyhippuric Acid – 5-Hydroxyindole-3-Acetic Acid – 5-Hydroxyindole-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 – (\pm)-Lorazepam – Lormetazepam – Lysergic Acid Diethylamide^[D] – Medazepam – Melanin – Meperidine – Mephentermine – Meprobamate – Mescaline – *dl*-Methamphetamine – (\pm)-Methadone – (+)-Methamphetamine – Methaqualone – (S)-6-Methoxy- α -Methyl-2-Naphthaleneacetic Acid – 2-Methyl-3-(3,4-Dihydroxyphenyl)-*dl* & *l*-Alanine – (\pm)-3,4-Methylenedioxyamphetamine – (\pm)-3,4-Methylenedioxymethamphetamine – Methylphenidate – Methypylon – Metoclopramide – (\pm)-Metoprolol – Morphine – Morphine-3- β -D-Glucuronide, Nafcillin – Nalorphine – Naloxone – Naltrexone – Naphazoline – α & β -Naphthaleneacetic Acid – Netilmicin – Niacinamide – Nialamide – Nicotinic Acid – Nifedipine – Nitrazepam –

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Nomifensine – Norcodeine – Nordoxepin^[B] - Norethindrone - Normorphine^[B] - Nortriptyline – Noscapine – Nyldrin – 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 , (\pm)- α & β -Phenylethylamine – (\pm)-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 – Trimethobenzamide – Trimethoprim – Trimipramine – Triprolidine – Tyramine – Urea – Uric Acid – Vancomycin – (\pm)-Verapamil – Zomepirac.

^[A] No interference was observed when the compound was tested to 25 μ g/ml

^[B] No interference was observed when the compound was tested to 10 μ g/ml

^[C] No interference was observed when the compound was tested to 10 μ g/ml

BIBLIOGRAPHY AND SUGGESTED REFERENCES

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