One-Step THC Test

For in vitro Diagnosis Use

INTENDED USE

The One-Step THC Test is a lateral flow, one-step immunoassay for the qualitative detection of 11-nor-tetrahydrocannabinol-9-THC-carboxylic acid in human urine at a cut-off of 50ng/ml. This product is used to obtain a visual, qualitative result and is intended for professional use. The assay should not be used without proper supervision and is not intended for over the counter sale to lay persons.

This assay provides only a preliminary analytical test result. A more specific alternative chemical method must be used in order to obtain a confirmed analytical result. Gas chromatography/mass spectrometry (GC/MS) has been established as the preferred confirmatory method by the National Institute on Drug Abuse (NIDA). Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are indicated.

SUMMARY

Marijuana is a hallucinogenic agent derived from the flowering portion of the hemp plant. Smoking is the primary method of use of marijuana/cannabis, Higher doses used by abusers produce central nervous system effects, altered mood and sensory perceptions, loss of coordination, impaired short-term memory, anxiety, paranoia, depression confusion, hallucinations and increased heart rate. A tolerance to the cardiac and psychotropic effects can occur, and withdrawal syndrome produces restlessness, insomnia, anorexia and nausea.

When marijuana is ingested, the drug is metabolized by the liver. The primary urinary metabolite of marijuana is 11-nor-△9-THC-9-carboxylic acid, and its glucuronide. This means that the presence of detected cannabinoids, including the primary carboxyl metabolite, in the urine indicate marijuana/cannabis use.

Urine based screening tests for drugs of abuse range from simple immunoassay tests to complex analytical procedures. The speed and sensitivity of immunoassays have made them the most widely accepted method for screening urine for drugs of abuse. One-Step THC Test is based on the principle of highly specific immunochemical

Reactions of antigens and antibodies are used for the analysis of specific compounds in biological fluids. This test is a rapid, visual, competitive immunoassay that can be used for the qualitative detection of 11-nor-△9-THC-9-carboxylic acid in human urine at 50ng/ml cut-off concentration.

PRINCIPLE

The One-Step THC Test is a one-step immunoassay in which a chemically labeled drug (drug conjugate) competes with the drug which may be present in urine for limited antibody binding sites. The test device contains a membrane strip which was pre-coated with drug conjugate on the test band. A colored anti-THC monoclonal antibody-colloidal gold conjugate pad is placed at the right end of the membrane. In the absence of drug in the urine, the solution of colored antibody-colloidal gold conjugate and urine moves upward, chromatographically by capillary action, across the membrane. This solution then migrates to the immobilized drug conjugate zone on the test band region. The colored antibody-colloidal gold conjugate then attaches to the drug conjugate to form a visible line as the antibody complexes with the drug conjugate. Therefore, the formation of a visible precipitant in the test zone occurs when the test urine is negative for the drug. When the drug is present in the urine, the drug/metabolite antigen competes with the drug conjugate on the test band region for limited antibody sites on the anti-THC monoclonal antibody-colloidal gold conjugate. When a sufficient concentration of drug is present, it will fill the limited antibody binding sites. This will prevent attachment of the colored antibody-colloidal gold conjugate to the drug-conjugate zone on the test band region. Therefore, absence of the color band on the test region indicates a positive result.

A control band with a different antigen/antibody reaction is also added to the immunochromatographic membrane strip at the control region (c) to indicate that the test has performed properly. This control line should always appear regardless of the presence of drug of metabolite. This means that negative urine will produces two colored bands, and positive urine will produce only one band. The presence of this colored band in the control region also serves as verification that 1) sufficient volume has been added, and 2) that proper flow was obtained.

MATERIALS SUPPLIED

1. 50individually wrapped test which include one desiccant each. Each test contains a membrane coated with drug conjugate and a colloidal gold conjugate pad coated with anti-THC monoclonal antibody.
2. One instruction sheet.

MATERIALS REQUIRED BUT NOT PROVIDED

1. Specimen collection container
2. Timer

STORAGE AND STABILITY

The test kit should be stored at room temperature 2-30℃ (36-86℉) in the sealed pouch for the duration of the shelf-life.

PRECAUTIONS

FOR IN VITRO DIAGNOSTIC USE.

For professional use only.

Urine specimens may be potentially infectious. Proper handling and disposal methods should be established.

Avoid cross-contamination of urine samples by using a new specimen collection container and specimen pipette for each urine sample.

SPECIMEN COLLECTION AND HANDLING

The One-Step THC Test is formulated for use with urine specimens. Fresh urine does not require any special handling or pretreatment. Urine samples should be collected such that testing can be performed as soon as possible after the specimen collection, preferably during the same day. the specimen may be refrigerated at 2-8℃ for 2 days, or frozen at -20℃ for a longer period of time. Specimens that have been refrigerated must be equilibrated to room temperature prior to testing. Specimens previously frozen must be thawed, equilibrated to room temperature, and mixed thoroughly prior to testing.

Note: Urine specimens and all materials coming in contact with them should be handled and disposed of as if capable of transmitting infection. Avoid contact with skin by wearing gloves and proper laboratory attire.

TEST PROCEDURE

Review "Specimen collection" instructions. Test strips, patient's samples, and controls should be brought to room temperature (20-30℃) prior to testing. Do not open pouches until ready to perform the assay.

1. Remove the test strip from its protective pouch (bring the test to room temperature before opening the pouch to avoid condensation of moisture on the membrane), and label the strip with patient or control number.
2. Immerse the test strip in the urine sample with the arrow end pointing toward the urine. Do not immerse the strip above the printed MAX line. After a minimum of 10 seconds, remove the test strip from the urine and lay flat on a non-absorptive clean surface. Alternatively, the test strip may be left in the test sample, as long as the strip is not immersed above the MAX line. A separate test strip must be for each sample or control.
3. **Read result between 3 to 8 minutes after the addition of samples.** Do not read result after 10 minutes.

INTERPRETATION OF RESULTS

Negative
Two pink-rose lines (bands) are visible in the control ("C") and test ("T") areas of the test window. The intensity of the test line may be less than that of the control line; this still means negative result.

Positive
The control line appears in the test window, but the test line is not visible.

Invalid
The test is invalid if the control line is not visible. The test failed, or the test procedure was not followed properly. Verify the test procedure and repeat the test with a new testing strip.

Note: A very faint line in the test region indicates that the THC in the samples is near the cut-off level for the test. These should be re-tested or confirmed with a more specific method before a positive determination is made.

LIMITATIONS OF PROCEURE

The assay is designed for use with human urine only.

A positive result with the tests indicates the presence of a drug/metabolite only and does not indicate or measure intoxication.

There is a possibility that technical or procedural errors as well as other substances and factors not listed may interfere with the test and cause false results. See SPECIFICITY for lists of substances that will produce positive results, or that do not interfere with test performance.

If it is suspected that the samples have been mislabeled or tampered with, a new specimen should be collected and the test should be repeated.

QUALITY CONTROL

Good laboratory practice recommends the use of control materials to ensure proper kit performance. Quality control specimens are available from commercial sources. When testing the positive and negative controls, use the same assay procedure as with a urine specimen.

PERFORMANCE CHARACTERISTICS

Accuracy

The One-Step THC Test was evaluated in comparison to a commercially available one-step immunoassay at a cut-off 50ng/ml.

One hundred (100) urine samples, collected from presumed non-user volunteers, have been tested by both procedures with 100% agreement.

In a separate study, sixty two (62) urine samples, obtained from a clinical laboratory where they were screened and confirmed as positive by the commercially available immunoassay and GC/MS, were tested by One-Step THC Test. The concentration of 11-nor-△9-THC-9-carboxylic acid in the urine samples were ranged from 30 to 300ng/ml. Of the fifteen (15) samples with 11-nor-△9-THC-9-carboxylic acid concentrations from 60 to 80ng/ml, all were found to be positives by both procedures (100% agreement). Of the thirty two (32) samples with 11-nor-△9-THC-9-carboxylic acid concentration ≥80ng/ml, all were found to be positives by both procedures (100% agreement). Of the fifteen (15) samples with 11-nor-△9-THC-9-carboxylic concentration from 33 to 42ng/ml, all were found to be negatives by both procedures (100% agreement).

Reproducibility

The reproducibility of the One-Step THC Test was evaluated at four different sites using blind controls. Of the sixty samples with a carboxylic acid concentration of 25ng/ml, all were determined negatives. Of the sixty samples with carboxylic acid concentration of 75ng/ml, all were determined positive.

Precision

The precision of the One-Step THC Test was determined by conducting the test with spiked controls. The control at the 25ng/ml should give a negative result and the control at the 75ng/ml should give a positive result.

11-nor-△9--THC-9-carboxylic acid Conc. (ng/ml)	Number Tested	Correct Result	%Correct Result
25	60	60	100
75	60	60	100

Specificity

The specificity for the One-Step THC Test was tested by adding various drugs, drug metabolites, and other compounds that are likely to be present in urine. All compounds were prepared in drug-free normal human urine.

The flowing structurally related compounds produced positive results when tested at levels equal to or greater than the concentrations listed below.

Compound	Concentration (ng/ml)
11-nor-△8-THC--9-carboxylic acid	50
11-nor-△9-THC--9-carboxylic acid	50
11-hydroxy-9-tetrahydrocannabinol	2,500
△8-tetrahydrocannabinol	7,500
△9-tetrahydrocannabinol	10,000
Cannabinol	10,000

The following compounds were found not to cross-react when tested at concentrations up to 100μg/ml.

Acetaminophen
Acetone
Albumin
Amitriptyline
Ampicillin
Aspartame
Aspirin
Atropine
Benzocaine
Bilirubin
Caffeine
Chloroquine
(+)-Chlorpheniramine
(+/-)-Chlorpheniramine
Creatine
Dexbrompheniramine
Dextromethorphan
4-Dimethyaminoantipyrine
Dopamine
(+/-)-Ephedrine
(-)-Ephedrine
(+)-Epinephrine
Erythromycin
Ethanol
Furosemide
Glucose
Guaiacol
Glyceryl
Ether
Hemoglobin
Imipramine
(+/-)-Isoproterenol
Lidocaine
(1R,S)-(-)-N-Methyl-Ephedrine
(+)-Naproxen
(+/-)-Norephedrine
Oxalic Acid
Penicillin-G
Pheniramine
Phenothiazine
l-Phenylephrine
Phenylethylamine
Procaine
Quinidine
Ranitidine
Riboflavin
Sodium Chloride
Sulindac
Tyramine
Vitamin C

Email:info@clinihealth.co.za
Web:www.clinihealth.co.za
Complaints/compliments/suggestions
Private Bag X12 Pretoria West 0117
Phone:027 114210702