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SERATEC® Drug Screen THC

REF DSC-THC

A visual one-step immunoassay for the qualitative detection of the cannabinoid metabolite 11-nor-Δ^9-tetrahydrocannabinol-carboxylic acid in human urine. For professional *In Vitro* diagnostic use only.

INTENDED USE

The SERATEC® Drug Screen THC is a lateral flow, one-step immunoassay for the qualitative detection of 11-nor-Δ^9-THC-carboxylic acid in human urine at a cut-off of 50 ng/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 of Drug Abuse (NIDA). Clinical considerations and professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are indicated.

BACKGROUND

Cannabinoids are hallucinogenic agents derived from the flowering portion of the hemp plant. The active ingredient of cannabinoids is tetrahydrocannabinol (THC). Cannabis can be taken by smoking (marihuana) or orally. The abuse of cannabis can result in hallucinations and euphoric mood elevations that are often accompanied by silliness, spontaneous laughter and an increase in reaction time. Furthermore the user may experience a loss of coordination, an impaired short-term memory, anxiety, paranoia, depression, confusion and an increased heart rate. Frequent use generally results in a tolerance towards the psychotropic and somatic effects. Abrupt withdrawal of the drug can produce withdrawal symptoms like restlessness, insomnia, anorexia and nausea.
THC is metabolized in the liver and is excreted with the urine predominantly as 11-nor-Δ^9-THC-carboxylic acid or as glucuronid a short time after its consumption. 11-nor-Δ^9-THC-carboxylic acid has a half-life of 24 hours and can detected 1-5 days after 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. The SERATEC® Drug Screen THC is based on the principle of the highly specific immunochemical reactions of antigens and antibodies which 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-Δ^9-THC-carboxylic acid in human urine at 50 ng/ml cut-off concentration.

PRINCIPLE

The SERATEC® Drug Screen THC is a one-step immunoassay in which a chemically labelled 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-11-nor-Δ^9-THC-carboxylic acid 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 the colored antibody-colloidal gold conjugate and urine moves upward, chromatographically by capillary action, across the membrane. This solution migrates to the immobilized drug conjugate zone on the test band region. The colored antibody-colloidal gold conjugate 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-11-nor-Δ^9-THC-carboxylic acid 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 colored 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 and metabolite. This means that **negative** urine will produce **two** colored bands, and **positive** urine will produce only **one** band. The presence of this colored band in the control region also serves as 1) verification that sufficient volume has been added, and 2) that proper flow was obtained.

STORAGE AND STABILITY

The test kit is to be stored refrigerated or at room temperature +4 – +30 °C (38-86 °F) in the sealed pouch for the duration of the shelf life.

PRECAUTIONS

- For single *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.
- Do not use test device if the pouch is damaged
- The components of the test of animal origin (e.g. antibodies) do not cause any danger if the test is used according to the instructions.

MATERIALS SUPPLIED IN THE KIT

- Test devices with disposable pipettes
- One instruction sheet

MATERIALS REQUIRED

- Specimen collection container
- Timer

SPECIMEN COLLECTION AND HANDLING

The SERATEC® Drug Screen THC 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°C for 2 days, or frozen at -20°C 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.

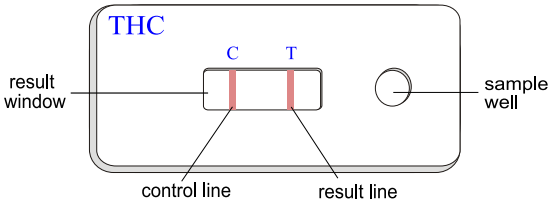
TEST PROCEDURE

Review “Specimen Collection“ instructions. Test device, patient’s samples, and controls should be brought to room temperature (20-30°C) prior to testing. Do not open pouches until ready to perform the assay.

1. Remove the test device from its protective pouch (bring the device to room temperature before opening the pouch to avoid condensation of moisture on the membrane). Label the device with patient or control identification.

2. Draw the urine sample to the line marked on the pipette (approximately 0.2 ml). Dispense the entire contents into the sample well. Use a separate pipette and device for each sample or control.

3. Read result between **3 to 8 minutes** after the addition of sample. Do not read result after 8 minutes.



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INTERPRETATION OF RESULTS

Negative result:

Two colored lines appear in the viewing window. The line in the test region (**T**) is the drug probe line; the line in the control region (**C**) is the control line, which indicates proper performance of the device. The color intensity of the test line may be weaker or stronger than that of the control line.

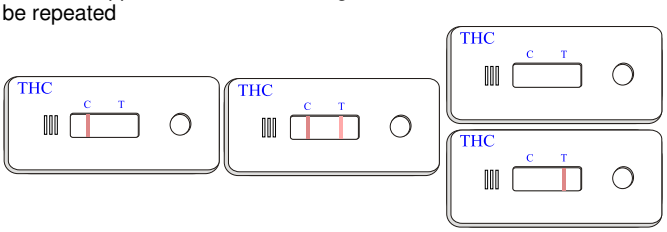
Note: A weak test line indicates that the 11-nor-d-9-tetrahydrocannabinol-carboxylic acid concentration is close to the cut-off level. In this case the test should be repeated or the urine sample should be tested with a more specific method.

Positive result

Only **one** colored line appears in the control region (C). The **absence** of a test line indicates a positive result.

Invalid:

If no line appears in the control region the test is invalid and should be repeated



Positive Negative Invalid

LIMITATIONS OF PROCEDURE

- The assay is designed for use with human urine only.
- A positive result with the test 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 (see SPECIFITY) may interfere with the test and cause false results.
- If it is suspected that the samples have been mislabelled or tampered with, a new specimen should be collected.

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*

*to adjust the concentration of 11-nor-Δ^9-THC-carboxylic acid in the non-clinical samples the Sigma Drug Standard N6893 was diluted into drug-free human urine.

A. Accuracy

The accuracy of the SERATEC® Drug Screen THC was evaluated in comparison to a commercially available immunoassay at a cut-off of 50 ng/ml. 120 urine samples, collected from presumed non-user volunteers, were tested by both procedures with 100% agreement in the negative results.

In a separate study, 72 urine samples obtained from a clinical laboratory, where they had been screened and confirmed as positive by the commercially available immunoassay and by GC/MS, were tested with the SERATEC® Drug Screen THC. 11-nor-Δ^9-THC-carboxylic acid concentrations ranged between 34.7 and 298 ng/ml. 15 samples with 11-nor-Δ^9-THC-carboxylic acid concentrations between 61.2 and 74.8 ng/ml showed positive results. 49 samples with 11-nor-Δ^9-THC-carboxylic acid concentrations > 75 ng/ml were reliably tested as positive. Within a concentration range of 34.7 to 44.6 ng/ml (8 samples) the SERATEC® test results were negative.

With the data obtained from the clinical specimens the performance characteristics of the test were calculated:

Diagnostic sensitivity:	100 %
Diagnostic specificity:	100 %
Positive predictive value:	100 %
Negative predictive value:	100 %
Reproducibility:	100 %

B. Reproducibility

The reproducibility of the SERATEC® Drug Screen THC test was evaluated at four different sites using blind controls. 60 of the samples containing 25 ng/ml 11-nor-Δ^9-THC-carboxylic acid showed negative results. 60 samples with 11-nor-Δ^9-THC-carboxylic acid concentrations of 100 ng/ml were determined as positive. Of the 60 samples containing 11-nor-Δ^9-THC-carboxylic acid at the cut-off level of 50 ng/ml, 20% tested positive, 10% tested negative, and 70% were determined as (+/-), showing a very faint test line.

C. Precision

The precision of the test was determined with blind controls of the following 11-nor-Δ^9-THC-carboxylic acid concentrations: 25; 37.5; 62.5; 75 ng/ml, respectively.

Conc. (ng/mL)	samples	correct results	in %
25.0	50	50 (-)	100
37.5	50	50 (-)[1]	100
62.5	50	35 (+)[2]	70
75.0	50	50 (+)	100

1: including 13 (+/-) results 2: the remaining 15 tests showed (+/-) results

D. Specificity

The specificity for the SERATEC® Drug Screen THC 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 following 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-Δ^9-THC-carboxylic acid*	50
11-Hydroxy-Δ^9THC	2,500
Δ^8THC	7,500
Δ^9THC	10,000
Cannabinol	10,000
Cannabidiol	100,000

* cut-off

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

Acetaminophen, Acetone, Albumin, Amitriptyline, Ampicillin, Aspartame, Aspirin, Atropine, Benzocaine, Bilirubin, Caffeine, Chloroquine, (+)-Chlorpheniramine, (+/-)-Chlorpheniramine, Creatine, Dexbrompheniramine, Dextromethorphan, 4-Dimethylaminoantipyrine, Dopamine, (+/-)-Ephedrine, (-)-Ephedrine, (+)-Epinephrine, Erythromycin, Ethanol, Furosemide, Glucose, Guaiacol-Glyceryl-Ether, Hemoglobin, Imipramine, (+/-)-Isoproterenol, Lidocaine, (1R,2S)-(-)-N-Methyl-Ephedrine, (+)-Naproxen, (+/-)-Norephedrine, Oxalic acid, Penicillin-G, Pheniramine, Phenothiazine, L-Phenylephrine, β-Phenylethylamine, Procaine, Quinidine, Ranitidine, Riboflavin, Sodium chloride, Sulindac, Tyramine, Vitamin C

SUGGESTED READING

1. Baselt, R.C. Disposition of Toxic Drugs and Chemicals in Man, Biomedical Publications, 1982

2. Urine Testing for Drugs of Abuse. National Institute on Drug Abuse (NIDA), Research Monograph 73, 1986

3. Fed. Register, Department of Health and Human Services, Mandatory Guidelines for Federal Workplace Drug Testing Programs, 53, 69, 11970, 1988

4. McBay, A.J. Clin. Chem. 33, 33B-40B, 1987

5. Gilman, A.G., & Goodman, L.S. The Pharmacological Basis of Therapeutics, eds. MacMillan Publishing, New York, NY, 1980.

Symbols

For single use only

Expiry date

Store at room temperature

IVD For in-vitro diagnostic use only

LOT Lot number

June 2009

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