RapidTech Drug Screen THC

A visual one-step immunoassay for the qualitative detection of 11-nor-Δ^9-Tetrahydrocannabinol-9-carboxylic acid (THC) in human urine. For professional in-vitro diagnostic use only.

INTENDED USE

Genix RapidTech One Step Drug Screen THC is a lateral flow, one-step immunoassay for the qualitative detection of 11-nor-Δ^9-Tetrahydrocannabinol-9-carboxylic acid (THC) in human urine at a cut-off of 50 ng/ml.

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 judgement 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 porting 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 syndromes produces restlessness, insomia, anorexia and nausea.

When marijuana is ingested, the drug metabolized by the liver. The primary urinary metabolite of marijuana is 11-nor-Δ^9-Tetrahydrocannabinol-9-carboxylic acid (THC), 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. The RapidTech One Step 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 THC in human urine at 50 ng/ml cut off concentration.

PRINCIPLE

Genix RapidTech One Step Drug Screen THC is a one-step immunoassay in which a chemically labeled drug (drug-protein 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 antibody-colloidal gold conjugate is place at the end of the membrane. The colored antibody-colloidal gold conjugate moves along with urine, chromatographically by capillary action, across the membrane. In the absence of drug in the urine, the colored antibody colloidal gold conjugate attaches to the drug-protein conjugate on the test band region to form a visible line as the antibody/drug-protein conjugate complexes. Therefore, the formation of a visible precipitant in the test band region 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-protein conjugate on the test band region for the limited antibody sites. When a sufficient amount 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-protein conjugate zone on the test band region. Therefore, a`bsence of the color band on the test region indicates a **positive** result.

A control or reference band with a different antigen/ antibody reaction is also added to the immunochromatographic membrane strip to indicate that the test is performed properly. This control line should always appear regardless of the presence of drug or 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.

STORAGE AND STABILITY

The test kit should be stored refrigerated or at room temperature 2 C to-30 C in the sealed pouch for the duration of the shelf-life.

PRECAUTIONS

1. For *in-vitro* diagnostic use.
2. For professional use only.
3. Urine specimens may be potentially infectious. Proper handling and disposal methods should be established.
4. Avoid cross-contamination of urine samples by using a new specimen collection container and specimen pipette for each urine sample.

REAGENTS AND MATERIALS SUPPLIED

1. **25** individually pouched test strips
2. One instruction sheet.

MATERIAL REQUIRED BUT NOT PROVIDED

1. Specimen collection container
2. Timer

SPECIMEN COLLECTION AND HANDLING

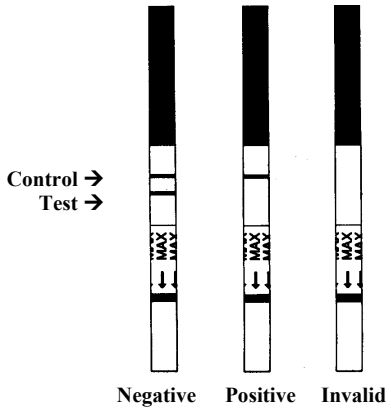
The Genix RapidTech One Step Drug Screen THC is formulated for use with urine specimens. Fresh urine does not require any special handling or pretreatment. Urine samples should be collected such that testing can be performed as soon as possible after the specimen collection, preferably during the same day. The specimen may be refrigerated at 2°C to 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 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 it is infectious and capable of transmitting infection. Avoid contact with skin by wearing gloves and proper laboratory attire.

TEST PROCEDURE

1. Review "Specimen Collection" instructions. Test device, patient's samples, and controls should be brought to room temperature (20°C to 30°C) prior to testing. Do not open pouches until ready to perform the assay.
2. Remove the test strip from the sealed pouch immediately before use. Label the strip with patient or control identification.
3. Immerse the strip into the urine with the arrow end pointing towards the urine. **Do not immerse pass the arrow pointed maximum line.** Take the strip out after a minimum of 10 seconds and lay the strip flat on a clean, dry, non-absorbent surface (e.g. mouth of the urine container).
4. Coloured band(s) will appear. Depending on the concentration of COC in the test specimen, negative results may be observed in as short as 10-30 seconds. However, to confirm **positive** results, the complete reaction time of 5 minutes is required. **Do not interpret results after 10 minutes.**

INTERPRETATION OF RESULTS



Negative:
Two colored lines should be observed. The line in the test region **(T)** is the drug probe line; the line in the control region **(C)** is the control line, which is used to indicate proper performance of the device. **The color intensity of the test line may be weaker or stronger than that of the control line.**

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

Invalid:
No line appears in the control region. Under no circumstances should a positive

sample be identified until the control line forms in the viewing area. If the control line does not form, the test result is inconclusive and the assay should be repeated.

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

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.

LIMITATIONS OF PROCEDURE

- The assay is designed for use with human urine only.
- A positive result with any of 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 or 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.

PERFORMANCE CHARACTERISTICS

Sensitivity

The following compounds were tests at the cut-off concentrations indicated. The cross reaction (calculated in percentage) is indicated in the following table.

Test	Compounds tested	Cut-off (ng/ml)	Cross Reactivity
Cannabinoid	11-nor-Δ^9-THC-9-COOH	50	100
	11-nor-Δ^8-THC-9-COOH	37.5	133
	11-hydroxy-Δ^9-THC	5000	1
	Δ^8-Tetrahydrocannabinol	15000	0.33
	Δ^9-Tetrahydrocannabinol	25000	0.20

Interference testing

The following substances did not interfere with RapidTech Plus DOA-4 test panels.

Glucose	2000 mg/dl
Human albumin	2000 mg/dl
Human hemoglobin	10 mg/dl
Urea	4000 mg/dl
Uric acid	10 mg/dl

Specificity

The following compounds show no cross-reactivity at concentration up to 100 µg/ml unless specified.

Acetaminophen	4-Acetamidophenol
Acetylsalicylic acid	Amikacin
Amitriptyline	Amobarbital
Arterenol	Aspartame
Ascorbic acid	Atrophine
Caffeine	Camphor
Chloroquine	Chlopheniramine
Cortisone	Deoxyephedrine
Dextromethorphan	Digitoxin
Digoxin	Diphenhydramine
Ecgonine	Ecgonine methyl ester
Ephedrine	Epinephrine
Gentisic	Guaiacol glycer ester
Histamine	Hydrochlorothiazide
Homatrophine	Imipramine
Ibuprofen	Isoproterenol
Ketamine	Lidocaine
Meperidine	Methadone
Methaqualone	Methylphenidate
Neomycin	Niacinamide
Perphenazine	Penicillin G
Phenylethylamine-α	Phenylpropanolamine
Promethazine	Pseudoephedrine
Quinine antidine	Salicylic acid
Tetracycline	Tetrahydrozoline
Theophyline	Thioridazine
Trifluoperazine	Tryptophan
Tyramine	

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