**THC-U23**

# Marijuana THC Rapid Test Device (Urine)

## INTENDED USE

The THC Rapid Test Device (Urine) is a rapid visual immunoassay for the qualitative presumptive detection of THC metabolites (11-nor-$\Delta^9$-THC-9-carboxylic acid) in human urine specimens.

| Parameter | Calibrator | Cut-off (ng/mL) |
|---|---|---|
| THC 25 (Marijuana) | Marijuana | 25 |
| THC 50 (Marijuana) | Marijuana | 50 |
| THC 150 (Marijuana) | Marijuana | 150 |
| THC 200 (Marijuana) | Marijuana | 200 |

## INTRODUCTION

Marijuana, cannabis or tetra-hydro-cannabinol (THC) 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 co-ordination, 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-$\Delta^9$-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.

## PRINCIPLE

The THC Rapid Test Device (Urine) has been designed to detect the THC metabolites through visual interpretation of color development in the internal strip. The membrane was immobilized with THC conjugates on the test region, and the sample pad was pre-coated with colored anti-THC metabolites antibodies colloidal gold conjugates. After specimens were added, the gold-conjugates move along the membrane chromatographically by capillary action and antibodies get to the test region. If there is no drug molecule in the urine the antibody gold conjugate would attach to the drug conjugate to form a visible line. Therefore, the formation of a visible precipitant in the test region occurs when the urine is negative for the drug. If THC metabolites are present in the urine, the drug antigen competes with the immobilized drug conjugate on the test region for limited antibody sites. In case of sufficient concentration of the drug, it fills the limited antibody binding sites. This will prevent attachment of the colored antibody-colloidal gold conjugate to the drug conjugate zone on the test region. Therefore, absence of the colored band on the test region indicates a positive result. Appearance of a colored band at the control region serves as a procedural control. This indicates that proper volume of specimen has been added and membrane wicking has occurred.

## REAGENTS

Each test consists of a reagent strip mounted in a plastic housing. The amount of each antigen and/or antibody coated on the strip is less than 0.001 mg for antigen conjugates and goat anti-rabbit IgG antibodies, and less than 0.0015 mg for antibody components.

The control zone of each test contains goat anti-rabbit IgG antibody. The test zone of each test contains drug-bovine protein antigen conjugate, and the conjugate pad of each test contains monoclonal anti-drug antibody and rabbit antibody-colored particle complex.

## MATERIALS

### Materials Provided

- Individually packed test devices
- Package insert
- Disposable pipettes

### Materials Required but Not provided

- Positive and negative controls
- Timer
- Centrifuge

## PRECAUTIONS

- For professional *in vitro* diagnostic use only.
- Do not use after expiration date indicated on the package. Do not use the test if its foil pouch is damaged. Do not reuse tests.
- This kit contains products of animal origin. Certified knowledge of the origin and/or sanitary state of the animals does not totally guarantee the absence of transmissible pathogenic agents. It is therefore, recommended that these products be treated as potentially infectious, and handled observing the usual safety precautions (do not ingest or inhale).
- Avoid cross-contamination of specimens by using a new specimen collection container for each specimen obtained.
- Read the entire procedure carefully prior to performing any tests.
- Do not eat, drink or smoke in the area where the specimens and kits are handled. Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout the procedure and follow the standard procedures for proper disposal of specimens. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed.
- Humidity and temperature can adversely affect results.
- The used testing materials should be discarded in accordance with local, state and/or federal regulations.

## STORAGE AND STABILITY

- The kit should be stored at 2-30°C until the expiry date printed on the sealed pouch.
- The test must remain in the sealed pouch until use.
- **Do not freeze.**
- Care should be taken to protect the components of the kit from contamination. Do not use if there is evidence of microbial contamination or precipitation. Biological contamination of dispensing equipment, containers or reagents can lead to false results.

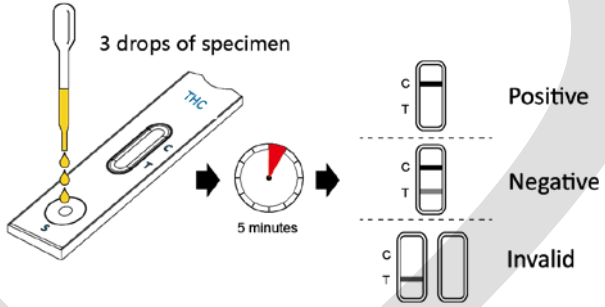
## SPECIMEN COLLECTION AND STORAGE

- The THC Rapid Test Device (Urine) is intended only for use with human urine specimens.
- Collected urine specimens must be put in clear and dry containers.
- Perform the testing immediately after the specimen collection. Do not leave the specimens at room temperature for prolonged periods. Specimens may be stored at 2-8°C for up to 48 hours. For long term storage, specimens should be kept below -20°C.
- Bring specimens to room temperature prior to testing. Frozen specimens must be completely thawed and mixed well prior to testing. Avoid repeated freezing and thawing of specimens.
- Pack the specimens in compliance with applicable regulations for transportation of etiological agents, in case they need to be shipped.

## PROCEDURE

**Bring tests, specimens, and/or controls to room temperature (15-30°C) before use.**

1. Remove the test from its sealed pouch, and place it on a clean, level surface. Label the test with patient or control identification. For best results, the assay should be performed within one hour.
2. Using the provided disposable pipette, transfer 3 drops of specimen (approximately 120 µL) to the specimen well (S) of the device and start the timer.
   **Avoid trapping air bubbles in the specimen well (S), and do not add any solution to the result area.**
   As the test begins to work, color will migrate across the membrane.
3. Wait for the colored band(s) to appear. The result should be read at 5 minutes. Do not interpret the result after 10 minutes.




## INTERPRETATION OF RESULTS

**POSITIVE: Only one colored band appears, in the control region (C).** No apparent colored band appears in the test region (T).

**NEGATIVE: Two colored bands appear on the membrane.** One band appears in the control region (C) and another band appears in the test region (T).

**INVALID: Control band fails to appear.** Results from any test which has not produced a control band at the specified read time must be discarded. Please review the procedure and repeat with a new test. If the problem persists, discontinue using the kit immediately and contact your local distributor.

**NOTE:**

1. The intensity of color in the test region (T) may vary depending on the concentration of analytes present in the specimen. Therefore, any shade of color in the test region should be considered negative. Note that this is a qualitative test only, and cannot determine the concentration of analytes in the specimen.
2. Insufficient specimen volume, incorrect operating procedure or expired tests are the most likely reasons for control band failure.

## QUALITY CONTROL

- Internal procedural controls are included in the test. A colored band appearing in the control region (C) is considered an internal positive procedural control, confirming sufficient specimen volume and correct procedural technique.
- External controls are not supplied with this kit. It is recommended that positive and negative controls be tested as a good laboratory practice to confirm the test procedure and to verify proper test performance.

## LIMITATIONS OF THE TEST

1. The THC Rapid Test Device (Urine) is for professional *in vitro* diagnostic use, and should be used for the qualitative detection of THC metabolites only.
2. The THC Rapid Test Device (Urine) provides only a quantitative, preliminary analytical result. A secondary analytical method must be used to obtain a confirmed result. Gas chromatography/mass spectrophotometry (GC/MS) is the preferred confirmatory method.
3. Please take the specificity and the cross reactivity into account for evaluation
4. A positive result with any of the tests indicates the presence of a drug/metabolite only, and does not indicate or measure intoxication.
5. A negative result may not necessarily indicate drug-free urine. Negative results can be obtained when drug is present but below the cut-off level of the test.
6. 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.
7. The test is designed for use with human urine only. Due to absence of ions and other components in pure water the usage or pure water for test could lead to false or invalid results.
8. The test does not distinguish between drugs of abuse and certain medications.

## PERFORMANCE CHARACTERISTICS

**A. Accuracy**

The accuracy of the THC test was compared and checked against a commercially available test with a cut-off value of 50 ng/ml. 120 urine samples taken from volunteer test persons who claim to be non-consumers was examined under both tests. The results were 100% in agreement.

**B. Reproducibility**

The reproducibility of the THC test was verified by blind tests performed at a four different locations. Of the 60 samples with 11-nor-$\Delta^9$-THC-9-carboxylic acid concentration of 25 ng/ml, all were determined negatives. Of the 60 samples with 11-nor-$\Delta^9$-THC-9-carboxylic acid concentration of 100 ng/ml, all were determined positives.

**C. Precision**

Test precision was determined by blind tests with control solutions. Controls with 11-nor-$\Delta^9$-THC-9-carboxylic acid concentration of 25 ng/ml should yield a negative result and controls with 11-nor-$\Delta^9$-THC-9-carboxylic acid concentration of 75 ng/ml should provide a positive result..

**D. Specificity**

The specificity of the Ecotest Drug Screen THC Test was tested with the substances listed below, all of which can be found in a normal urine specimen.

**The following compounds with a similar chemical structure yield a positive result at the specified concentration:**

| THC25 related compounds | Concentration (ng/ml) |
|---|---|
| 11-nor-Δ9-THC-9-COOH | 25 |
| Cannabinol | 15,000 |
| 11-nor-Δ8-THC-9-COOH | 25 |
| Δ8-Tetrahydrocannabinol | 10,000 |
| Δ9-Tetrahydrocannabinol | 10,000 |

| THC50 related compounds | Concentration (ng/ml) |
|---|---|
| 11-nor-$\Delta^9$-THC-9-COOH | 50 |
| 11-nor-$\Delta^8$-THC-9-COOH | 50 |
| $\Delta^8$-Tetrahydrocannabinol | 15000 |
| $\Delta^9$-Tetrahydrocannabinol | 15000 |
| Cannabinol | 20000 |

| THC150 related compounds | Concentration (ng/ml) |
|---|---|
| 11-nor-Δ8-THC-9-COOH | 150 |
| Cannabinol | 20,000 |
| 11-nor-Δ9-THC-9-COOH | 150 |
| Δ8-Tetrahydrocannabinol | 20,000 |
| Δ9-Tetrahydrocannabinol | 20,000 |

| THC200 related compounds | Concentration (ng/ml) |
|---|---|
| 11-nor-Δ8-THC-9-COOH | 200 |
| 11-nor-Δ9-THC-9-COOH | 200 |
| Δ8-Tetrahydrocannabinol | 30,000 |
| Δ9-Tetrahydrocannabinol | 30,000 |
| Cannabinol | 20,000 |

**With exception of the above, for the respective parameter listed positive-reacting drugs resp. drug metabolites, all following listed compounds reacted negative up to a concentration of 100 µg/ml.**

| | | |
|---|---|---|
| (-)-Ephedrine | Chlorpheniramine | Oxalic Acid |
| (+)-Naproxen | Creatine | Penicillin-G |
| (+/-)-Ephedrine | Dextromethorphan | Pheniramine |
| 4-Dimethyllaminoantiyrine | Dextrorphan tartrate | Phenothiazine |
| Acetaminophen | Dopamine | Procaine |
| Acetone | Erythromycin | Protonix |
| Albumin | Ethanol | Pseudoephedrine |
| Amitriptyline | Furosemide | Quinidine |
| Ampicillin | Glucose | Ranitidine |
| Aspartame | Guaiacol Glyceryl Ether | Sertraline |
| Aspirin | Hemoglobin | Tyramine |
| Benzocaine | Imipramine | Trimeprazine |
| Bilirubin | (+/-)-Isoproterenol | Venlafaxine |
| b-Phenylethyl-amine | Methadone | Ibuprofen |
| Caffeine | Vitamin C (Ascorbic Acid) | Lidocaine |
| Chloroquine | | |

## LITERATURE REFERENCES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## GLOSSARY OF SYMBOLS

| | | | |
|---|---|---|---|
| ρ | Catalog number | 0 | Temperature limitation |
| ι | Consult instructions for use | Λ | Batch code |
| I | In vitro diagnostic medical device | ε | Use by |
| µ | Manufacturer | T | Contains sufficient for <n> tests |
| σ | Do not reuse | A | Authorized representative in the European Community |
| Y | CE marking according to IVD Medical Devices Directive 98/79/EC | | |

ECOTEST

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