

## DRUG ALERT

### MARIJUANA THC URINE Rapid SCREENING Test

In home one step drug screen test.

A rapid one step screening test for detection of Marijuana (THC) in Urine.

*For in vitro diagnostic use only.*

#### INTENDED USE

The Drug Alert marijuana (THC) urine screening test is a rapid chromatographic immunoassay for the detection of 11-nor- $\Delta^9$ -THC-9 COOH (THC metabolite) in human urine at a cut-off concentration of 50 ng/mL.

This assay provides only a preliminary analytical test result. A more specific alternate chemical method must be used in order to obtain a confirmed analytical result. Gas chromatography/mass spectrophotometry (GC/MS) is the preferred confirmatory method. Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are used.

#### MARIJUANA THC

THC ( $\Delta^9$ -tetrahydrocannabinol) is the primary active ingredient in cannabinoids (Marijuana). When smoked or orally administered, it produces euphoric effects. Users have impaired short term memory and slowed learning. Users may also experience transient episodes of confusion and anxiety. Long term relatively heavy use may be associated with behavioral disorders. The peak effect of smoking Marijuana occurs in 20-30 minutes and the duration is 90-120 minutes after one cigarette. Elevated levels of urinary metabolites are found within hours of exposure and remain detectable for 3-10 days after smoking. The main metabolite excreted in the urine is 11-nor- $\Delta^9$ -tetrahydrocannabinol-9-carboxylic acid ( $\Delta^9$ -THC-COOH).

The test is a rapid urine screening test that can be performed without the use of an instrument. The test utilizes a monoclonal antibody to selectively detect elevated levels of Marijuana in urine. The THC Urine Screening rapid test yields a positive result when the concentration of Marijuana in urine exceeds 50 ng/mL.

This is the suggested screening cut-off for positive specimens set by **Australian/New Zealand Standards:**

**AS/NZ 4308:2008**

#### PRINCIPLE

The test is a rapid chromatographic immunoassay based on the principle of competitive binding. Drugs which may be present in the urine specimen compete against the drug conjugate for binding sites on the antibody. During testing, a urine specimen migrates upward by capillary action. Marijuana, if present in the

urine specimen below 50 ng/mL, will not saturate the binding sites of the antibody coated particles in the test cassette. The antibody coated particles will then be captured by immobilized THC conjugate and a visible colored line will show up in the test line region. The colored line will not form in the test line region if the Marijuana level is above 50 ng/mL because it will saturate all the binding sites of anti-Marijuana antibodies. A drug-positive urine specimen will not generate a colored line in the test line region because of drug competition, while a drug-negative urine specimen or a specimen containing a drug concentration less than the cut-off will generate a line in the test line region. To serve as a procedural control, a colored line will always appear at the control line region indicating that proper volume of specimen has been added and membrane wicking has occurred.

#### REAGENTS

The test cassette contains mouse monoclonal anti-Marijuana antibody-coupled particles and Marijuana-protein conjugate. A goat antibody is employed in the control line system.

#### PRECAUTIONS

- For in vitro diagnostic use only. Do not use after the expiration date.
- The test cassette should remain in the sealed pouch until use.
- All specimens should be considered potentially hazardous and handled in the same manner as an infectious agent.

#### STORAGE AND STABILITY

The kit can be stored at room temperature or refrigerated (2-30°C). The test cassette is stable through to the expiration date printed on the sealed pouch. The test cassette must remain in the sealed pouch until use. **DO NOT FREEZE.** Do not use beyond the expiration date.

#### SPECIMEN COLLECTION AND PREPARATION

The urine specimen must be collected in a clean and dry container. Urine collected at any time of the day may be used. Urine specimens exhibiting visible precipitates should be centrifuged, filtered, or allowed to settle to obtain a clear supernatant for testing.

#### Specimen Storage

Urine specimens may be stored at 2-8°C for up to 48 hours prior to testing. For prolonged storage, specimens may be frozen and stored below -20°C. Frozen specimens should be thawed and mixed before testing.

#### MATERIALS

##### Materials Provided

- Test cassette
- Disposable dropper

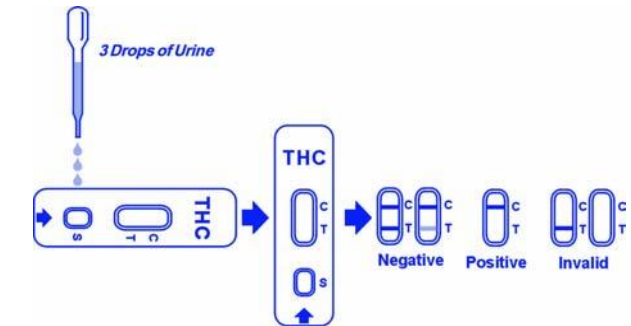
##### Materials Required But Not Provided

- Specimen collection container
- Timer

#### DIRECTIONS FOR USE

**Allow the test cassette, urine specimen, and/or controls to equilibrate to room temperature (15-30°C) prior to testing.**

- 1 Remove the test cassette from the sealed pouch and use it as soon as possible.
- 2 Place the test cassette on a clean and level surface. Hold the dropper vertically and **transfer 3 full drops of urine** (approx. 100 $\mu$ l) to the specimen well of the test cassette, and then start the timer. Avoid trapping air bubbles in the specimen well. Refer to the illustration below.
- 3 Wait for the red line(s) to appear. The result should be **read at 5 minutes**. Do not interpret the result after 10 minutes.



#### INTERPRETATION OF RESULTS

(Please refer to the illustration above)

**NEGATIVE:** \* **Two lines appear.** One red line should be in the control region (C), and another apparent red or pink line should be in the test region (T). This negative result indicates that the Marijuana concentration is below the detectable level of 50 ng/mL.

\*NOTE: The shade of red in the test region (T) may vary, but it should be considered negative whenever there is even a faint pink line.

**POSITIVE:** **One red line appears in the control region (C).** No line appears in the test region (T). This positive result indicates that the Marijuana concentration is above the detectable level of 50 ng/mL.

**INVALID: Control line fails to appear.** Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test with a new test cassette. If the problem persists, discontinue using the test kit immediately and contact the supplier.

#### QUALITY CONTROL

A procedural control is included in the test. A red line appearing in the control region (C) is considered an internal procedural control. It confirms sufficient specimen volume and correct procedural technique. Control standards are not supplied with this kit; however it is recommended that positive and negative controls be tested as good laboratory testing practices to confirm

the test procedure and to verify proper test performance.

#### **LIMITATIONS**

1. The THC Urine Screening test provides only a qualitative, 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.<sup>1,2</sup>
2. It is possible that technical or procedural errors, as well as other interfering substances in the urine specimen may cause erroneous results.
3. Adulterants, such as bleach and/or alum, in urine specimens may produce erroneous results regardless of the analytical method used. If adulteration is suspected, the test should be repeated with another urine specimen.
4. A positive result indicates presence of the drug or its metabolites but does not indicate level of intoxication, administration route or concentration in urine.
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. Test does not distinguish between drugs of abuse and certain medications.

#### **WEB ADDRESS**

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CE

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