

THC Rapid Test Cassette (Whole Blood/Serum/Plasma) Package Insert

A rapid test for the qualitative detection of Marijuana in human whole blood or serum or plasma. For medical and other professional in vitro diagnostic use only.

【INTENDED USE】

The THC Rapid Test Cassette (Whole Blood/Serum/Plasma) is a lateral flow chromatographic immunoassay for the detection of Marijuana in whole blood or serum or plasma at a cut-off concentration of 35 ng/mL. This test will detect other related compounds, please refer to the analytical Specificity table in this package insert.

This assay provides only a qualitative, preliminary analytical test result. A more specific alternate chemical method must be used in order to obtain a confirmed analytical result. Gas chromatography/mass spectrometry (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.

【SUMMARY】

THC (9-tetrahydrocannabinol) is the primary active ingredient in cannabis (marijuana). When smoked or orally administered, THC produces euphoric effects. Users have impaired short-term memory and slowed learning. They may also experience transient episodes of confusion and anxiety. long-term, relatively heavy use may be associated with behavioral disorders. The peak effect of marijuana administered by smoking 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 whole blood/serum/plasma is 11-nor-(9-tetrahydrocannabinol-9-carboxylic acid (THC-COOH)¹.

【PRINCIPLE】

The THC Rapid Test Cassette (Whole blood/Serum/Plasma) is an immunoassay based on the principle of competitive binding. Drugs that may be present in the whole blood/serum/plasma specimen compete against the drug conjugate for binding sites on the antibody. During testing, a whole blood/serum/plasma specimen migrates upward by capillary action. Marijuana, if present in the whole blood/serum/plasma specimen below the cut-off level, will not saturate the binding sites of the antibody in the test. The antibody coated particles will then be captured by immobilized Marijuana-protein 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 exceeds the cut-off level because it will saturate all the binding sites of anti-Marijuana antibodies. A drug-positive whole blood/serum/plasma specimen will not generate a colored line in the test line region because of drug competition, while a drug-negative whole blood/serum/plasma 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 contains mouse monoclonal anti-Marijuana antibody coupled particles and Marijuana-protein conjugate. A goat antibody is employed in the control line system.

【PRECAUTIONS】

- For professional in vitro diagnostic use only. Do not use after the expiration date.
- Do not eat, drink or smoke in the area where the specimens or kits are handled.
- Do not use test if pouch is damaged.
- Handle all specimens as they contain infectious agents. Observe established precautions against microbiological hazards throughout testing 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 being tested.
- The used test should be discarded according to local regulations.
- Humidity and temperature can adversely affect results.

【STORAGE AND STABILITY】

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

【SPECIMEN COLLECTION AND PREPARATION】

- The THC Rapid Test Cassette can be performed using whole blood (from venipuncture or fingerstick).
- To collect **Fingerstick Whole Blood specimens**:
 - Wash the patient's hand with soap and warm water or clean with an alcohol swab. Allow to dry.
 - Massage the hand without touching the puncture site by rubbing down the hand towards the fingertip of the middle or ring finger.
 - Puncture the skin with a sterile lancet. Wipe away the first sign of blood.
 - Gently rub the hand from wrist to palm to form a rounded drop of blood over the puncture site.
 - Add the Fingerstick Whole Blood specimen to the test by using a **capillary tube**:
 - Touch the end of the capillary tube to the blood until filled to approximately 40 µL. Avoid air bubbles.
 - Place the bulb onto the top end of the capillary tube, then squeeze the bulb to dispense the whole blood to the specimen area of the test cassette.
- Testing should be performed immediately after the specimens have been collected. Do not leave the specimens at room temperature for prolonged periods. For long term storage, specimens should be kept below -20°C. Whole blood or serum or plasma collected by venipuncture should be stored at 2-8°C if the test is to be run within 2 days of collection. Do not freeze whole blood or serum or plasma specimens. Whole blood/serum/plasma collected by

fingerstick should be tested immediately.

- Bring specimens to room temperature prior to testing. Frozen specimens must be completely thawed and mixed well prior to testing. Specimens should not be frozen and thawed repeatedly.
- If specimens are to be shipped, they should be packed in compliance with local regulations covering the transportation of etiologic agents.

【MATERIALS】

| | | | |
|--|--------------|----------|------------------|
| • Test Cassettes | • Droppers | • Buffer | • Package Insert |
| • Specimen collection containers | • Centrifuge | • Timer | |
| • Lancets (for fingerstick whole blood only) | | | |
| • Heparinized capillary tubes and dispensing bulb (for fingerstick whole blood only) | | | |

【DIRECTIONS FOR USE】

Allow the test, specimen and buffer to reach room temperature (15-30°C) prior to testing.

- Bring the pouch to room temperature (15-30°C) before opening it. Remove the cassette from the sealed pouch and use it within one hour.
- Place the cassette on a clean and level surface.

For serum or plasma specimen:

- Hold the dropper vertically and transfer **1 full drop of serum or plasma** (approximately 40 µL), then add **2 drops of buffer** (approximately 80 µL) to the specimen well of the cassette, and then start the timer. Avoid trapping air bubbles in the specimen well.
- For Venipuncture Whole Blood specimen:**
- Use a capillary tube: Fill the capillary tube and **transfer approximately 40 µL of fingerstick whole blood specimen** to the specimen well of test cassette, then add **2 drops of buffer** (approximately 80 µL) and start the timer.
- For Fingerstick Whole Blood specimen:**
- To use a capillary tube: Fill the capillary tube and **transfer approximately 40 µL of fingerstick whole blood specimen** to the specimen well of test cassette, then add **2 drops of buffer** (approximately 80 µL) and start the timer.

- Wait for the colored line(s) to appear. **Read results at 5 minutes**. Do not interpret the result after 10 minutes.

【INTERPRETATION OF RESULTS】

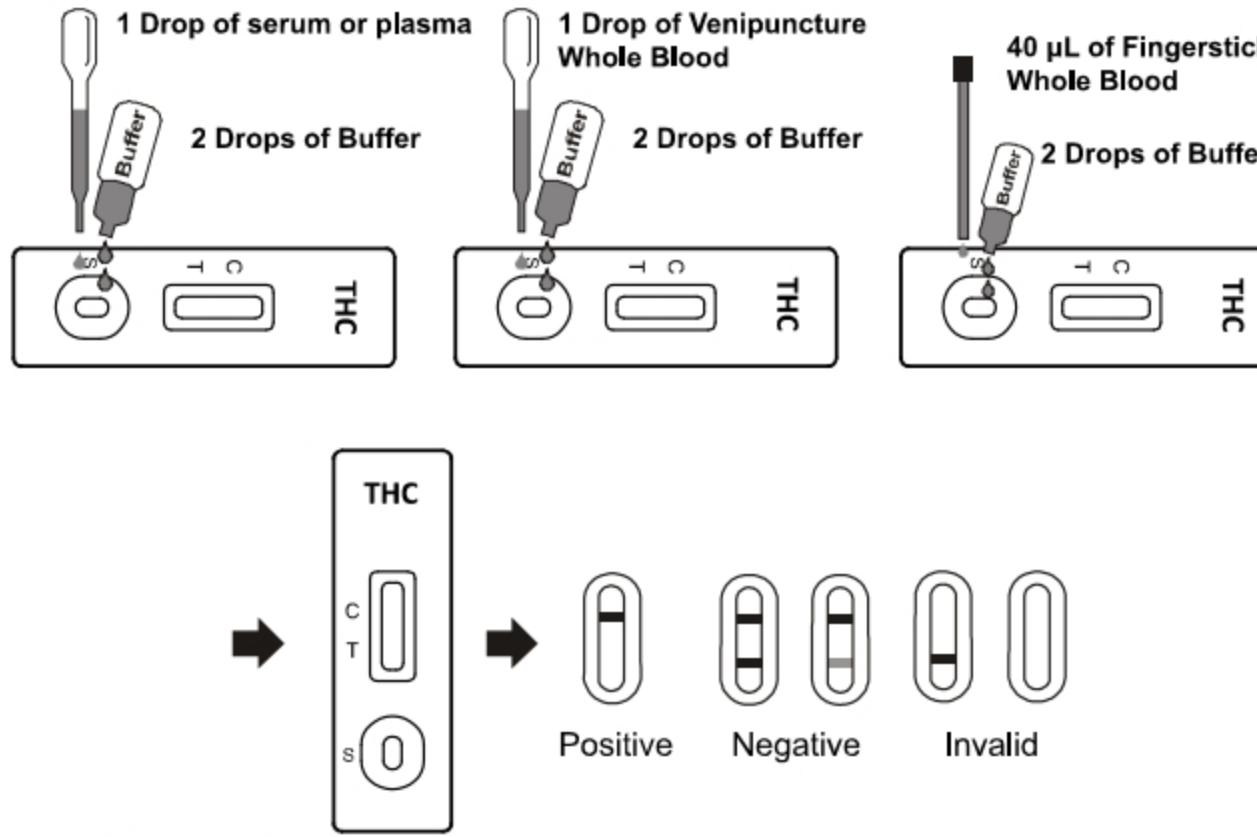
(Please refer to the illustration)

NEGATIVE: Two colored lines appear. One colored line should be in the control line region (C) and another colored line should be in the test line region (T). This negative result indicates that the Marijuana concentration is below the detectable cut-off level.

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

POSITIVE: One colored line appears in the control line region (C). No line appears in the test line region (T). This positive result indicates that the Marijuana concentration exceeds the detectable cut-off level.

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. If the problem persists, discontinue using the test kit immediately and contact your local distributor.



【QUALITY CONTROL】

A procedural control is included in the test. A colored line appearing in the control region (C) is the 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 a good laboratory practice to confirm the test procedure and to verify proper test performance.

【LIMITATIONS】

- The THC Rapid Test Cassette (Whole blood/Serum/Plasma) provides only a qualitative, preliminary analytical result. A secondary analytical method must be used to obtain a confirmed result. Gas chromatography/mass spectrometry (GC/MS) is the preferred confirmatory method.²
- It is possible that technical or procedural errors, as well as other interfering substances in the whole blood or serum or plasma specimen may cause erroneous results.

- A positive result indicates presence of the drug or its metabolites but does not indicate level of intoxication, administration route or concentration in whole blood or serum or plasma.
- A negative result may not necessarily indicate drug-free Whole blood/Serum/Plasma. Negative results can be obtained when drug is present but below the cut-off level of the test.
- Test does not distinguish between drugs of abuse and certain medications.

【PERFORMANCE CHARACTERISTICS】

Accuracy

A side-by-side comparison was conducted using the THC Rapid Test Cassette and GC/MS at the cut-off of 35ng/mL. Testing was performed on 90 clinical specimens previously collected from subjects present for Drug Screen Testing. The following results were tabulated:

Clinic Result of Whole Blood

| Method | GC/MS | | Total Results |
|-------------------------|----------|--------------|---------------|
| | Results | Positive | |
| THC Rapid Test Cassette | Positive | 24 | 25 |
| | Negative | 2 | 65 |
| Total Results | | 26 | 90 |
| % Agreement | | 92.3% | 98.4% |
| 96.7% | | | |

Clinic Result of Serum or Plasma

| Method | GC/MS | | Total Results |
|-------------------------|----------|--------------|---------------|
| | Results | Positive | |
| THC Rapid Test Cassette | Positive | 24 | 25 |
| | Negative | 2 | 65 |
| Total Results | | 26 | 90 |
| % Agreement | | 92.3% | 98.4% |
| 96.7% | | | |

Analytical Sensitivity

A drug-free whole blood/serum/plasma pool was spiked with Marijuana at the following concentrations of $\pm 50\%$ cutoff and 3x cutoff, The data are summarized below:

For whole blood:

| THC Concentration (ng/mL) | Percent of Cut-off | n | Visual Result | |
|---------------------------|--------------------|----|---------------|----------|
| | | | Negative | Positive |
| 0 | 0 | 30 | 30 | 0 |
| 17.5 | -50% | 30 | 30 | 0 |
| 35 | Cut-off | 30 | 15 | 15 |
| 52.5 | +50% | 30 | 0 | 30 |
| 105 | 3X | 30 | 0 | 30 |

Analytical Specificity

The following table lists compounds that are positively detected in Whole blood/Serum/Plasma by the THC Rapid Test Cassette (Whole blood/Serum/Plasma) at 5 minutes.

Compound

| Compound | Concentration (ng/mL) |
|--------------------------------|-----------------------|
| Cannabinol | 25,000 |
| 11-nor- Δ^9 -THC-9 COOH | 25 |
| 11-nor- Δ^9 -THC-9 COOH | 35 |
| Δ^9 -THC | 12,000 |
| Δ^9 -THC | 12,000 |

Precision

A study was conducted at three hospitals by untrained operators using three different lots of product to demonstrate the within run, between run and between operator precision. An identical panel of coded specimens, containing no marijuana, and 50% marijuana above and below the 35ng/ml cut-off was provided to each site. The following results were tabulated:

| THC Concentration (ng/mL) | n per Site | Site A | | Site B | | Site C | |
|---------------------------|------------|--------|---|--------|---|--------|---|
| | | - | + | - | + | - | + |
| 0 | 10 | 10 | 0 | 10 | 0 | 10 | 0 |
| 17.5 | 10 | 8 | 2 | 9 | 1 | 9 | 1 |
| 52.5 | 10 | 1 | 9 | 1 | 9 | 2 | 8 |

Cross-Reactivity

A study was conducted to determine the cross-reactivity of the test with compounds in either drug-free whole blood/serum/plasma or marijuana positive whole blood/serum/plasma. The following compounds show no cross-reactivity when tested with the THC Rapid Test Cassette (Whole blood/Serum/Plasma) at a concentration of 100 µg/mL.

Non Cross-Reacting Compounds