



For professional *in vitro* diagnostic use only

Marijuana (THC) Rapid Test Package Insert

INTENDED USE & SUMMARY

The Marijuana (THC) Rapid Test is a lateral flow chromatographic immunoassay for the detection of detection of 11-nor- Δ^9 -THC-9 COOH (THC metabolite) in human urine at a cut-off concentration of 50 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 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.

THC (Δ^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- Δ^9 -tetrahydrocannabinol-9-carboxylic acid (Δ^9 -THC-COOH).

The Marijuana (THC) Rapid 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 Marijuana (THC) 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 the Substance Abuse and Mental Health Services Administration (SAMHSA, USA).

PRINCIPLE

The Marijuana (THC) Rapid 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 strip. The antibody coated particles will then be captured by immobilized Marijuana 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 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.

COMPOSITION

Each test kit contains test strip/device (dropper)/panel and package insert.

Materials required but not provided: timer, Specimen collection container.

STORAGE AND STABILITY

- Store the test kit in a cool, dry place between 2-30°C. Keep away from light. Exposure to temperature and / or humidity outside the specified conditions may cause inaccurate results.
- Do not freeze.** Use the test kit at temperatures between 15-30°C.
- Use the test kit between 10-90% humidity.
- Do not use the test kit beyond the expiration date (printed on the foil pouch and box).

Note: All expiration dates are printed in Year-Month-Day format. 2022-06-18 indicates June 18, 2022.

WARNINGS, PRECAUTIONS AND LIMITATIONS

- For professional *in vitro* diagnostic use only. Do not use the test after the expiration date.
- The test 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.
- 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.
- The Marijuana (THC) Rapid Test 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.
- It is possible that technical or procedural errors, as well as other interfering substances in the urine specimen may cause erroneous results.
- 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.
- A positive result indicates presence of the drug or its metabolites but does not indicate level of intoxication, administration route or concentration in urine.

- 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.
- Test does not distinguish between drugs of abuse and certain medications.

SPECIMEN COLLECTION AND PREPARATION

1) Urine Assay

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.

2) Specimen Storage

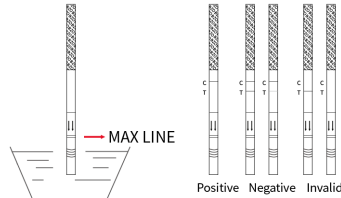
Urine specimens may be stored at 2-8°C for up to 48 hours prior to assay. For prolonged storage, specimens may be frozen and stored below -20°C. Frozen specimens should be thawed and mixed before testing.

TEST PROCEDURE

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

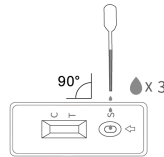
[For Strip]

- Bring the pouch to room temperature before opening it. Remove the test strip from the sealed pouch and use it as soon as possible.
- With arrows pointing towards the urine specimen, immerse the test strip vertically in the urine specimen in such a way that urine does not cross MAX line on the test strip for 10-15 seconds. See the illustration below.
- Wait for the red line(s) to appear. The result should be **read at 5 minutes**. Do not interpret the result after 10 minutes.



[For Device]

- Bring the pouch to room temperature before opening it. Remove the test device from the sealed pouch and use it as soon as possible.
- Place the test device on a clean and level surface. Hold the dropper vertically and transfer 3 full drops of urine (approx. 120 μ L) to the specimen well (S) of the test device, and then start the timer. Avoid trapping air bubbles in the specimen well (S). See illustration below.
- Wait for the red line(s) to appear. The result should be **read at 5 minutes**. Do not interpret the result after 10 minutes.

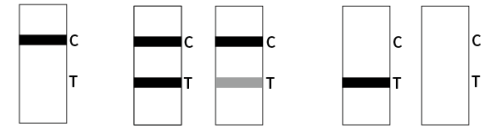


[For Panel]

- Bring the pouch to room temperature before opening it. Remove the test panel from the sealed pouch and use it as soon as possible.
- With the arrow pointing toward the urine specimen, immerse the test card vertically in the urine specimen for at least 10 to 15 seconds. Immerse the strip to at least the level of the wavy lines, but not above the arrow on the test card.
- Replace the cap and place the test card on a non-absorbent flat surface.
- 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 TEST RESULTS



Positive

Negative

Invalid

Positive: A colored line in the control line region (C) but no line in the test line region (T) for a specific drug indicates a positive result. This indicates that the drug concentration in the specimen exceeds the designated cut-off for that specific drug.

Negative: **Two distinct colored lines appear.** A colored line in the control line region (C) and a colored line in the test line region (T) for a specific drug indicate a negative result. This indicates that the drug concentration in the specimen is below the designated cut-off level for that specific drug.

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

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 using a new test panel. If the problem persists, discontinue using the lot immediately and contact your local distributor.

QUALITY CONTROL

Internal procedural controls are included in the test. A colored line appearing in the control region (C) is the internal procedural control. This procedural control line indicates that sufficient flow has occurred, and the functional integrity of the test device has been maintained. 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.

PERFORMANCE

1. Accuracy

A side-by-side comparison was conducted using the Marijuana (THC) Rapid Test and a leading commercially available THC Rapid Test. Testing was performed on 300 clinical specimens previously collected from subjects present for Drug Screen Testing. Ten percent of the specimens employed were either at -25% or +25% level of the cut-off concentration of 50 ng/mL Marijuana. Presumptive positive results were confirmed by GC/MS. The following results were tabulated:

| Method | Other THC Rapid Test | | Total Results |
|----------------------------|----------------------|----------|---------------|
| | Results | Positive | Negative |
| Marijuana (THC) Rapid Test | Positive | 159 | 0 |
| | Negative | 3 | 138 |
| Total Results | | 162 | 138 |
| % Agreement | | 98% | >99% |

When compared at 50 ng/mL cut-off with GC/MS, the following results were tabulated:

| Method | GC/MS | | Total Results |
|----------------------------|----------|----------|---------------|
| | Results | Positive | Negative |
| Marijuana (THC) Rapid Test | Positive | 140 | 19 |
| | Negative | 3 | 138 |
| Total Results | | 143 | 157 |
| % Agreement | | 98% | 88% |

2. Analytical Sensitivity

A drug-free urine pool was spiked with drugs to the concentrations at $\pm 50\%$ cut-off and $\pm 25\%$ cut-off. The results are summarized below.

A drug-free urine pool was spiked with Marijuana at the following concentrations: 0 ng/mL, 25 ng/mL, 37.5 ng/mL, 50 ng/mL, 62.5 ng/mL and 75 ng/mL. The result demonstrates >99% accuracy at 50% above and 50% below the cut-off concentration. The data are summarized below:

| Marijuana Concentration (ng/mL) | Percent of Cut-off | n | Visual Result | |
|---------------------------------|--------------------|----|---------------|----------|
| | | | Negative | Positive |
| 0 | 0 | 30 | 30 | 0 |
| 25 | -50% | 30 | 30 | 0 |
| 37.5 | -25% | 30 | 22 | 8 |
| 50 | Cut-off | 30 | 14 | 16 |
| 62.5 | +25% | 30 | 4 | 26 |
| 75 | +50% | 30 | 0 | 30 |

3. Analytical Specificity

The following tables list the concentrations of compounds (ng/mL) above which the Marijuana (THC) Rapid Test identified positive results at 5 minutes.

| Marijuana related Compound | Concentration (ng/mL) |
|---|-----------------------|
| 11-nor- Δ^9 -THC-9-COOH | 50 |
| 11-Hydroxy- Δ^9 -Tetrahydrocannabinol | 5000 |
| 11-Nor- Δ^9 -Tetrahydrocannabinol-9-COOH | 50 |
| Cannabinol | >100000 |
| Δ^9 -Tetrahydrocannabinol | 15000 |
| Δ^9 -Tetrahydrocannabinol | 15000 |
| Cannabidiol | >100000 |
| 11-Nor- Δ^9 -THC-carboxy glucuronide | 100 |
| (-)-11-nor-9-carboxy- Δ^9 -THC | 50 |

4. Precision

Three study sites are participating in the study. Tests were performed over a 10-day period by three operators at each site. There were two tests per day per concentration at each site for each lot to demonstrate the within run, between run and between operator precision. An identical panel of coded specimens containing, according to GC/MS, no Marijuana, 25% Marijuana above and below the cut-off, and 50% Marijuana above and below the 50 ng/mL cut-off was provided to each site. The results are given below:

| THC Concentration (ng/ml) | n per Site | Site A | | Site B | | Site C | |
|------------------------------|---------------|--------|----|--------|----|--------|----|
| | | - | + | - | + | - | + |
| 0 | 20 | 60 | 0 | 60 | 0 | 60 | 0 |
| 25 | 20 | 60 | 0 | 60 | 0 | 60 | 0 |
| 37.5 | 20 | 42 | 18 | 48 | 12 | 44 | 16 |
| 62.5 | 20 | 10 | 50 | 8 | 52 | 14 | 46 |
| 75 | 20 | 0 | 60 | 0 | 60 | 0 | 60 |

5. Effect of Specific Gravity

Fifteen urine specimens of normal, high, and low specific gravity ranges were spiked with 25 ng/mL and 75 ng/mL of Marijuana. The Marijuana (THC) Rapid Test was tested in duplicate using the fifteen neat and spiked urine specimens. The results demonstrate that varying ranges of urinary specific gravity do not affect the test results.

6. Effect of Urinary pH

The pH of an aliquoted negative urine pool was adjusted to a pH range of 5 to 9 in 1 pH unit increments and spiked with Marijuana to 25 ng/mL and 75 ng/mL. The spiked, pH-adjusted urine was tested with the Marijuana (THC) Rapid Test in duplicate. The results demonstrate that varying ranges of pH does not interfere with the performance of the test.

CROSS-REACTIVITY

A study was conducted to determine the cross-reactivity of the test with compounds in either drug-free urine or Marijuana positive urine. The following compounds show no cross-reactivity when tested with the Marijuana (THC) Rapid Test at a concentration of 100 µg/mL.

NON CROSS-REACTIVITY

| | | | |
|----------------------|------------------------|------------------|----------------------|
| Acetophenetidin | Cortisone | Isosuprine | d-Pseudoephedrine |
| N-Acetylprocainamide | I-Cotinine | Ketoprofen | Quinidine |
| Acetylsalicylic acid | Creatinine | Labetalol | Quinine |
| Aminopyrine | Deoxycorticosterone | Loperamide | Salicylic acid |
| Amoxicillin | Dextromethorphan | Meprobamate | Serotonin |
| Ampicillin | Diclofenac | Methoxyphenamine | Sulfamethazine |
| I-Ascorbic acid | Diffunisal | Methylphenidate | Sulindac |
| Apomorphine | Digoxin | Nalidixic acid | Tetracycline |
| Aspartame | Diphenhydramine | Naproxen | Tetrahydrocortisone, |
| Atropine | Ethyl-p-aminobenzoate | Niacinamide | 3-Acetate |
| Benzilic acid | β-Estradiol | Nifedipine | Tetrahydrocortisone |
| Benzoic acid | Estrone-3-sulfate | Norethindrone | Tetrahydrozoline |
| Bilirubin | Erythromycin | Noscapine | Thiamine |
| d,l-Brompheniramine | Fenoprofen | d,l-Octopamine | Thioridazine |
| Caffeine | Furosemide | Oxalic acid | d,l-Tyrosine |
| Cannabidiol | Gentisic acid | Oxolinic acid | Tolbutamide |
| Chloral hydrate | Hemoglobin | Oxymetazoline | Triamterene |
| Chloramphenicol | Hydralazine | Papaverine | Trifluoperazine |
| Chlorothiazide | Hydrochlorothiazide | Penicillin-G | Trimethoprim |
| d,l-Chlorpheniramine | Hydrocortisone | Perphenazine | d,l-Tryptophan |
| Chlorpromazine | o-Hydroxyhippuric acid | Phenelzine | Uric acid |
| Cholesterol | 3-Hydroxytyramine | Prednisone | Verapamil |
| Clonidine | d,l-Isoproterenol | d,l-Propanolol | Zomepirac |

REFERENCES

1. Tietz NW. Textbook of Clinical Chemistry. W.B. Saunders Company. 1986; 1735
2. Baselt RC. Disposition of Toxic Multi-Drugs and Chemicals in Man. 2nd Ed. Biomedical Publ., Davis, CA. 1982; 488
3. Hawks RL, CN Chiang. Urine Testing for Drugs of Abuse. National Institute for Drug Abuse (NIDA), Research Monograph 73, 1986

INDEX OF SYMBOLS

| | | | | | |
|--|---|--|--------------|--|-----------------------------------|
| | Consult instructions for use | | Use by | | Contains sufficient for <n> tests |
| | For <i>in vitro</i> diagnostic use only | | Lot number | | Catalog number |
| | Storage temperature limitations | | Manufacturer | | Do not reuse |
| | Authorized Representative | | | | |

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