



Marijuana (THC) Rapid Test Kit

Instructions For Use

PRODUCT NAME

Marijuana (THC) Rapid Test Kit

PACKAGE SPECIFICATION

20 tests/kit

INTENDED USE

FRENOVO Marijuana (THC) Rapid Test is a lateral flow, qualitative immunoassay. It is intended for qualitative detection of 11-nor- Δ 9-THC-9 COOH, a Marijuana metabolite with a minimum detection concentration of 50 ng / ml in human urine samples, and for the preliminary screening detection of Marijuana.

SUMMARY AND PRINCIPLES OF THE PROCEDURE

FRENOVO Marijuana (THC) Rapid Test uses the highly specific antibody & antigen reaction principle, as well as immunochromatography and colloidal gold labeling technology.

The test kit contains 11-nor- Δ 9-THC-9 COOH antibody labeled with colloidal gold, and 11-nor- Δ 9-THC-9 COOH antigen which is fixed in the test area (T) on the membrane. When the urine sample was dropped into the sample well, the urine sample was then chromatography upward under capillary effect. If the concentration of 11-nor- Δ 9-THC-9 COOH in urine is lower than 50ng/ml, the colloidal gold antibody cannot be combined with all 11-nor- Δ 9-THC-9 COOH. In this way, the colloidal gold antibody binding will be bound by 11-nor- Δ 9-THC-9 COOH antigen fixed on the membrane during the chromatography, and a purple red band will appear in the test area (T). If the concentration of 11-nor- Δ 9-THC-9 COOH in urine is higher than 50ng/ml, the colloidal gold antibody is bound to 11-nor- Δ 9-THC-9 COOH, so that (T) in the test area (T) there is no purple red band because the competitive reaction does not bind to 11-nor- Δ 9-THC-9 COOH antigen. Whether 11-nor- Δ 9-THC-9 COOH is present in urine, a purple red strip will appear in the quality control area (c). The purple red band in the quality control area (c) is the standard to determine whether there is enough urine sample, whether the chromatography process is normal, and also as the internal control standard of tests.

MATERIALS PROVIDED

Each kit contains:

- 1. Test Devices: 20 pieces test devices individually pouched.
- 2. Droppers: 20 pieces droppers of 25 ul
- 3. Package insert: 1 piece attached.

MATERIALS REQUIRED BUT NOT PROVIDED

- Timer or stopwatch.
- · Specimen collection containers
- Disposable gloves and/or protective clothing
- Micropipette

WARNINGS

- Read the package insert completely before using the product. The instructions must be followed carefully as not doing so may result in inaccurate results.
- 2. FRENOVO Marijuana (THC) Rapid Test is for diagnostic use only.
- 3. Perform test at room temperature.

PRECAUTIONS

- FRENOVO Marijuana (THC) Rapid Test is for professional use only.
- The package insert instructions must be followed to ensure optimum test performance.
- 3. The used test device should be discarded according to local regulations.

Handling Precautions

- Do not use if the kit box safety seal is absent, damaged or broken.
- 2. Do not use any device if the pouches have been perforated.
- 3. Each device is for single use only.
- 4. Do not use the kit past the expiration date (this date is printed on the kit box).
- Adequate lighting is required to read the test results.
- The result should be read immediately after the end of the 5 minutes incubation time following the addition of specimen and wash buffer solution. Do not read results beyond 10 minutes.

STORAGE INSTRUCTIONS

 FRENOVO Marijuana (THC) Rapid Test kit should be stored between 2-30°C and the shelf life is 24 months.

- If stored refrigerated, ensure that the pouched device is brought to room temperature before opening.
- Do not freeze the kit.

SAMPLE 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 supermatant for testing. Urine specimens may be stored at 2-8 $^{\circ}$ for up to 48 hours prior to testing. For prolonged storage, specimens may be frozen and stored below -20 $^{\circ}$. Frozen specimens should be thawed and mixed well before testing.

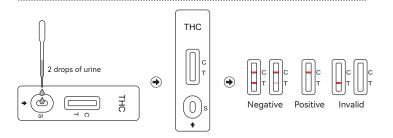
QUALITY CONTROL

An internal procedural control is included in the test. a colored line appearing in the control line region (C) is an internal valid procedural control, it confirming adequate membrane wicking. 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.

TEST PROCEDURE

Allow the test, urine specimen, and/or controls to reach room temperature (15-30 $^{\circ}$ C) prior to testing.

- 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 2 full drops of urine (approx.50 μL) to the specimen well of the test
 device, and then start the timer. Avoid trapping air bubbles in the specimen well.
 See the illustration below.
- 3. 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 above)

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

*NOTE: The shade of color in the test line region (T) will vary, but it should always be considered as 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 drug concentration exceeds the detectable 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 using a new cassette. If the problem persists, discontinue using the lot immediately and contact your local distributor.

LIMITATIONS

- FRENOVO 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.
- There is a possibility 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 does not indicate level or 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.
- 6. The test does not distinguish between drugs of abuse and certain medications.

A positive result may be obtained from certain foods or food supplements.

PERFORMANCE CHARACTERISTICS

Positive cutoff reference rang

According to the requirements of American drug abuse and mental health service administration (SAMHSA) for the cutoff value of Marijuana in urine, the detection threshold of THC is set at 50ng / ml.

Sensitivity and Specificity

Accuracy

A clinical study was conducted using FRENOVO Marijuana (THC) Rapid Testand GC/MS. Testing was performed on 150 pieces positive urine specimens and 150 pieces negative urine specimens previously collected and confirmed by GC/MS. The results indicated that FRENOVO Marijuana (THC) Rapid Testhas a high sensitivity and specificity as summarized below:

clinical study		GC/MS		Total Results
FRENOVO	Results	Positive	Negative	Total Results
Marijuana (THC) Rapid Test	Positive	150	0	150
	Negative	0	150	150
Total Results		150	150	300

Accuracy Results:

Clinical sensitivity > 99.00 % (95%Cl* 98.02 % to 100.0 %) Clinical specificity > 99.00 % (95%Cl* 98.02 % to 100.0 %) Accuracy> 99.00 % (95%Cl* 99.00 % to 100.0 %)

Analytical Sensitivity A piece of drug-free urine was spiked with drugs to the concentrations at $\pm\,50\%$ cut-off and $\pm\,25\%$ cut-off. Each titer was repeated 30 pieces of test. The results are summarized below.

Drug Conc.	THC50		
(Cut-off range)	POS/+	NEG/-	
0% Cut-off	0	30	
-50% Cut-off	0	30	
-25% Cut-off	0	30	
Cut-off	9	21	
+25% Cut-off	13	17	
+50% Cut-off	30	0	

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 FRENOVO Marijuana (THC) Rapid Test at a concentration of 100 µg/mL.

4-Acetamidophenol Ethyl-p-aminobenzoate Orphenadrine Acetope Ethyl-p-aminobenzoate Oxalic acid Acetophenetidin Etodolac Oxolinic acid Acetylsalicylic acid Famprofazone Oxymetazoline Albumin Fenoprofen Papaverine Alphanyrine Gentisic acid Penticillin Amoxicillin Gelucose Phenicillin Amoxapine Gelucose Phenicillin Amoxapine Gelucose Phenicillin Amoxapine Gelucose Phenicillin Amoxapine Hydraslacine Phenicillin Amoxapine Hydrochlorothiacide Prednisolone Alpomorphanic Prednisolone Quinacrine Benzicia acid	Non Cross-Reacting Compounds					
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Caffeine Isoproterenol Riboflavin Cannabidiol Isoxsuprine Salicylic acid Chloral Hydrate Kanamycin Serotonin Chloramphenicol Ketoprofen Seroquel Chloroquine Labetalol Sertraline Chlorothiazide Lidocaine Sodium Chloride Chloropromazine Lindane Sulfamethazine Chlorprothixene Lithium Sulindac Cholesterol Loperamide Tetracycline Cimetidine I-Thyroxine Tetrahydrocortison-3-acetate Clonidine Meperidine Tetrahydrocortison-3-acetate Clonidine Meperidine Tetrahydrocortison-3-acetate Clonidine Meprobamate Theophylline Cortisone Meprobamate Theophylline Cortisone Meprobamate Theophylline Deoxycorticosterone Methoxyphenamine Thioridazine Dextromethorphan Methoprolol phenylcyclopropylamine Trans-2-phenylcyclopropylamine Trass-2-phenylcyclopropylamine Dicyclomine N-			R(-) Deprenyl			
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INDEX OF SYBOML

IVD	In vitro diagnostic medical device	2	single-use, Please don't reuse it
₹	Use-by date	Πi	Consult instructions for use
\triangle	Cautions	***	Manufacturer
2°C 30°C	Temperature limit	LOT	Batch code
<u>~</u>	Date of manufacture	**	Keep Dry
*	Avoid overexposure to the sun	(S)	Don't use the product when the package is damaged
(€	CE mark	8	Biological risks

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