FRENOVO

Kratom (KRA) Rapid Test Kit

Instructions For Use

PRODUCT NAME

FRENOVO Kratom (KRA) Rapid Test Kit

PACKAGE SPECIFICATION

25 tests/kit

INTENDED USE

FRENOVO Kratom (KRA) Rapid Test is a lateral flow, qualitative immunoassay. It is intended for qualitative detection of Mitragynine, with a minimum detection concentration of 100 ng / ml in human urine samples, and for the preliminary screening detection of Kratom.

SUMMARY AND PRINCIPLES OF THE PROCEDURE

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

The test kit contains Mitragynine antibody labeled with colloidal gold, and Mitragynine 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 Mitragynine in urine is lower than 100ng/ml, the colloidal gold antibody can not be combined with all Mitragynine. In this way, the colloidal gold antibody binding will be bound by Mitragynine antigen fixed on the membrane during the chromatography, and a purple red band will appear in the test area (T). If the concentration of Mitragynine in urine is higher than 100ng/ml, the colloidal gold antibody is bound to Mitragynine, so that in the test area (T) there is no purple red band because the competitive reaction does not bind to Mitragynine antigen. Whether Mitragynine 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: 25 pieces test devices individually pouched.
2. Package insert: 1 piece attached.
3. Dropper：25 pieces of 25ul

MATERIALS REQUIRED BUT NOT PROVIDED

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

WARNINGS

1. 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 Kratom (KRA) Rapid Test is for diagnostic use only.
3. Perform test at room temperature.

PRECAUTIONS

1. FRENOVO Kratom (KRA) Rapid Test is for professional use only.
2. 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

1. 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).
5. Adequate lighting is required to read the test results.
6. 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

1. FRENOVO Kratom (KRA) Rapid Test kit should be stored between 2-30°C and the shelf life is 24 months.
2. If stored refrigerated, ensure that the pouched device is brought to room temperature before opening.
3. 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 supernatant for testing.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 well before testing.

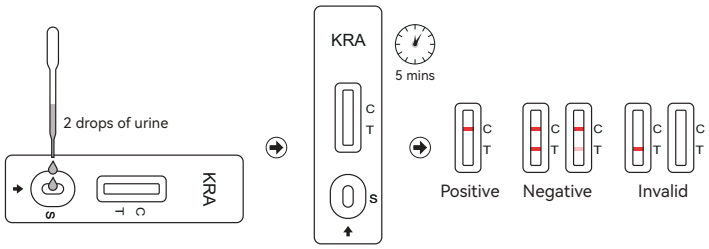
QUALITY CONTROL

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 (15-30ºC) prior to testing.

1. Bring the pouch to room temperature before opening it. Remove the test device from the sealed pouch and use it as soon as possible.
2. Place the test device on a clean and level surface. Hold the dropper vertically and transfer 2 full drops of urine 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

1. FRENOVO Kratom (KRA) 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.
2. There is a possibility 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 does not indicate level or 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. The test does not distinguish between drugs of abuse and certain medications.
7. A positive result may be obtained from certain foods or food supplements.

PERFORMANCE CHARACTERISTICS

Sensitivity and Specificity

Accuracy

A clinical study was conducted using FRENOVO Kratom (KRA) Rapid Test and 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 Kratom (KRA) Rapid Test has a high sensitivity and specificity as summarized below:

clinical study		GC/MS		Total Results
FRENOVO Kratom (KRA) Rapid Test	Results	Positive	Negative	
	Positive	150	2	152
	Negative	0	148	148
Total Results		150	150	300

Summary Results:

Clinical sensitivity > 99.00 % (97.57%～100.00%)
Clinical specificity = 98.67% (95.27%～99.84%)
Accuracy = 99.33% (97.61%～99.92%)

Cross-Reactivity

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

Non Cross-Reacting Compounds			
(-)-Epinephrine	Dextromethorphan	Lorazepam	Quinacrine
(R)-(−)-Phenyl ephrine	Diflunisal	MDEA	Quinine
(S)-(-)-Propranolol	Diphenhydramine	MDMA	S(-)-Methcathinone
6β-Naltrexol	Dopamine	MDPV	Salicylamide
Acetaminophen	Doxepin	Mephedrone	Secobarbital
Acetone	Erythromycin	Methadone	Seroquel
Alpha-Hydroxyhippuric acid	Estrone 3-sulfate	Methamphetamine	Serotonin
Amoxicillin	Fenoprofen	Methaqualone	Sertraline HCL
Amphetamine, AMP	Fentanyl	Mirtazapine	Sodium Oxalate
Ampicillin	Fludiazepam	N-Acetylprocainamide	Sulfamethazine
a-PVP	Fluvoxamine	Naltrexone	Sulindac
Aspartame	Gabapentin	Nortriptyline	Tetracycline
Aspirin	Guaifenesin	Octopamine	Tetrahydrocannabinol
Bilirubin	Hemoglobin	Oxolinic acid	Thiamine
Brompheniramine	Human Albumin	Oxycodone	Tolbutamide
Buspirone	Hydralazine	Oxymetazoline	Tramadol
Caffeine	Hydrocodon	Papaverine	Trans-2-phenylcyclopropylamine
Chloramphenicol	Ibuprofen	Pentylone	Trazodone
Chloroquine	Isoxsuprine	Perphenazine	Triamterene
Chlorothiazide	JWH-018	Phenelzine	Tryptamine
Chlorpheniramine	Kanamycin	Phenytoin	Tyrosine
Cholesterol	Ketoprofen	Prednisolone	Naloxone
Codeine	Loperamide	Pseudoephedrine	JWH-018 metabolites
Barbital	Paynantheine		

Analytical Specificity

The following table lists the concentration of compounds (ng/mL) that are detected positive in urine by FRENOVO Kratom (KRA) Rapid Test at 5 minutes.

Compounds	Conc. ng/ml
Mitragynine	100
7-Hydroxymitragynine	500

Analytical Sensitivity

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

Drug Conc. (Cut-off range)	KRA100	
	POS/+	NEG/-
0% Cut-off	0	30
-50% Cut-off	0	30
-25% Cut-off	4	26
Cut-off	16	14
+25% Cut-off	28	2
+50% Cut-off	30	0

INDEX OF SYBOML

IVD	In vitro diagnostic medical device		single-use, Please don't reuse it
	Use-by date		Consult instructions for use
	Cautions		Manufacturer
2°C 30°C	Temperature limit	LOT	Batch code
	Date of manufacture		Keep Dry
	Avoid overexposure to the sun		Don't use the product when the package is damaged
	Biological risks		

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