FRENOVO

Microalbuminuria (MAU) Rapid Test Kit

Instructions For Use

PRODUCT NAME

Microalbuminuria (MAU)Rapid Test Kit

PACKAGE SPECIFICATION

25 tests/kit

INTENDED USE

FRENOVO Microalbuminuria (MAU) Rapid Test is a lateral flow, qualitative immunoassay. It is intended for qualitative detection of albuminuria levels in urine in vitro diagnostic. It is used as a supplementary method in the diagnosis of chronic kidney injury(CKI).

SUMMARY AND PRINCIPLES OF THE PROCEDURE

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

The test kit contains albumin antibody labeled with colloidal gold, and albumin 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 albumin in urine is lower than 20mg/L, the colloidal gold antibody can not be combined with all albumin. In this way, the colloidal gold antibody will be bound by albumin antigen fixed on the membrane during the chromatography, and a purple red band will appear in the test area (T). If the concentration of albumin in urine is higher than 20mg/L, the colloidal gold antibody is bound to albumin, so that in the test area (T) there is no purple red band because the competitive reaction does not bind to Albumin antigen. Whether albumin 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. Droppers: 25 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

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 Microalbuminuria (MAU) Rapid Test is for diagnostic use only.
3. Perform test at room temperature.

PRECAUTIONS

1. FRENOVO Microalbuminuria (MAU) 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 Microalbuminuria (MAU) 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. 2 hours before collecting the urine specimens, should not consume a large amount of liquid or drinks to prevent getting inaccurate result. 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℃ for up to 48 hours prior to testing. For prolonged storage, specimens may be frozen and stored below -20℃. Frozen specimens should be thawed and mixed well before testing.

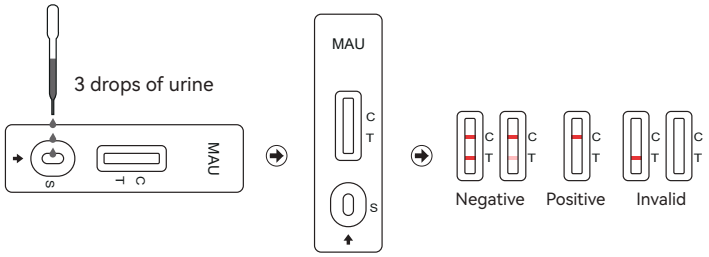
QUALITY CONTROL

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 3 full drops of urine (approx. 75 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 concentration of albumin 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 concentration of albumin 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. The test is only used for qualitative determination of albumin in urine. A positive result with the test indicates the albumin concentration in urine is more than 20mg/L, and does not necessarily indicate kidney injury.
2. The test kit provides a presumptive diagnosis. A conformed diagnosis should only be made by a physician after all clinical and laboratory findings have been evaluated.

PERFORMANCE CHARACTERISTICS

Accuracy

The accuracy of the Microalbumin Rapid Test kit was evaluated in comparison to a commercially available immunoassay at a cut-off of 20mg/L. 100 urine samples from volunteers were tested by both procedures and showed >98% agreement.

Sensitivity

The Microalbumin Rapid Test kit has a sensitivity of 20mg/L in urine.The result was summarized as below:

Specificity

The following compounds were found not to cross-react when tested at concentrations up to 1000 μg/ml:

Acetaminophen	Imipramine	Dopamine
(±)-Ephedrine	Bilirubin	Procaine
Acetone	(±)-Isoproterenol	Oxalic acid
(+)-Epinephrine	Caffeine	Quinidine
Amitriptyline	Lidocaine	Pheniramine
Erythromycin	Chloroquine	Sulindac
Ampicillin	D-Methamphetamine	(±)-Norephedrine
Ethanol	(±)-Chlorpheniramine	Riboflavin
L-Ascorbate	L-Methamphetamine	Penicillin-G
Furosemide	Creatine	Sodium chloride
Aspartame	(±)-3,4-Methylenedioxy	D-Phenylethylamine
Glucose	Dexbrompheniramine	Trimethobenzamide
Aspirin	methamphetamine (MDMA)	Phenothiazine
Guaiacol glyceryl ether	Dextromethorphan	Thioridazine
Atropine	N-Methyl-ephedrine	L-Phenylephrine
Hemoglobin	4-Dimethylaminoantipyrine	Trifluoperazine
Benzocaine	(+)-Naproxen	Ranitidine
Tyramine	--	--

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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