CE IVD

FRENOVO

Luteinizing Hormone (LH) Rapid Test Kit
Instructions For Use

PRODUCT NAME

Luteinizing Hormone (LH) Rapid Test Kit

PACKAGE SPECIFICATION

20 tests/kit

INTENDED USE

FRENOVO Luteinizing Hormone (LH) Rapid Test is a lateral flow, qualitative immunoassay. It is intended for detection of LH in specimens of urine samples, to predict the time of ovulation, to guide women of childbearing age to choose the best time of pregnancy or to guide the safe period of contraception.

SUMMARY AND PRINCIPLES OF THE PROCEDURE

A woman's body continuously produces a small amount of luteinizing hormone (LH). During the middle of the menstrual cycle, there is a sudden increase of this hormone followed by a rapid decline back to basal levels. While the maximal LH concentration before and after the surge is < 20 mIU/ml, LH levels from >30 to 100 mIU/ml are reached at peak times. This increase of the LH level, called LH surge, promotes the release of a mature egg from the ovary (ovulation). For most women, ovulation will occur within 24 - 36 hours after the first steep increase of the LH level. Immediately after the ovulation the egg is ready to be fertilised for a short time (appr. 12-24 hours). With FRENOVO Luteinizing Hormone (LH) Rapid Test, LH in urine will be determined for a time period of 5 days. In this time the test will detect if and when a LH surge occurs. The "most fertile days" of the menstrual period start after this LH surge. As sperms are fertile for about 3 days (rarely even 6 days) after sexual intercourse the fertile period can be limited to about 3-5 days before and 2 days after the surge.

FRENOVO Luteinizing Hormone (LH)) Rapid Test is an assay for detection of LH with using urine samples that utilizes immunochromatographic assay technology as its measurement principle. The test consists of a cassette device containing a separate region with immobilized mouse monoclonal anti-LH specific monoclonal antibody and reagent pads with mouse monoclonal anti-LH antibody binding gold colloid.

When LH is present in the sample, it is bound by specific antibodies immobilised at the test region of the membrane. This complex is then made visible by binding of another gold-labelled antibody, resulting in a colored line. The intensity of the test result line depends on the amount of LH in the urine sample.

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

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 Luteinizing Hormone (LH)) Rapid Test is for diagnostic use only.
   FRENOVO Luteinizing Hormone (LH)) Rapid Test is for professional use only.
3. Perform test at room temperature.

PRECAUTIONS

1. FRENOVO Luteinizing Hormone (LH)) 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 Luteinizing Hormone (LH)) 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.

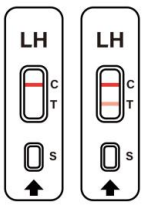
TEST PROCEDURE

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 (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.

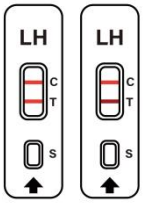
INTERPRETATION OF RESULTS

Negative result: One or two red bands appear. One is in the test area (T), the other is in the quality control area (C), but the T line is lighter than the C line, or

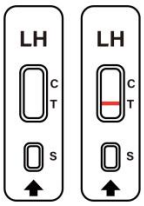


there is no T line. Shown as the pic.

Positive result: Two red bands appear. One is in the test area (T) and the other is in the quality control area (C). T line is stronger than C line, or C line and T line are equivalent. Shown as the pic.



Invalid result: if the quality control line C is not observed, it will be invalid regardless of whether there is detection line, and the test shall be conducted again. Shown as the pic.



LIMITATIONS

1. This reagent is only used for in vitro diagnosis.
2. This reagent is only used to detect human urine specimen. The results of other specimens may be wrong.
3. This reagent is only used for qualitative detection and cannot indicate the level of LH in the specimen.
4. This reagent is only a clinical auxiliary diagnostic tool. If the result is positive, it is recommended to use other methods for further examination in time and the doctor's diagnosis shall prevail.

PERFORMANCE CHARACTERISTICS

Positive cutoff reference range

The cutoff value of FRENOVO Luteinizing Hormone (LH)) Rapid Test is set at 25mIU / ml.

Accuracy

A clinical evaluation was conducted comparing the results obtained using the FRENOVO Luteinizing Hormone (LH) Rapid Test and another commercially available urine LH test. The study included 200 urine specimens and both assays identified 100 negative and 100 positive results. The results demonstrated 100% overall agreement (for an accuracy of > 99%) of the FRENOVO Luteinizing Hormone (LH) Rapid Test.

Cross-Reactivity

A study was conducted to determine the cross-reactivity of the test with compounds in either negative urine or positive urine. The test has been standardized to the W.H.O. Fourth International Standard (75/589). The addition of FSH (200 mIU/mL), and TSH (250 μIU/mL) to negative (0 mIU/mL LH and positive (25 mIU/mL LH) specimens showed no cross-reactivity with FRENOVO Luteinizing Hormone (LH)) Rapid Test .

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	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
CE	CE mark		Biological risks

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INSTRUCTION APPROVAL AND REVISION DATE

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