(LH) Luteinizing Hormone Rapid Test Kit

(Immunochromatography)

Product Name

(LH) Luteinizing Hormone Rapid Test Kit (Immunochromatography)

Intended Use

The reagent is used to detect the LH in urine qualitatively according to the principle of double antibody sandwich method.

Luteinizing Hormone (LH) is a glycoprotein hormone produced by the human anterior pituitary, including protein subunits of α and β. Its function is to promote ovarian synthesis and secretion of estrogen, stimulate maturation of follicular act synergistically with FSH （Follicle Stimulating Hormone）. Ovulation time can be predicted by the detection of LH peak.

Principle

The test utilizes antibodies including a monoclonal LH-β antibody and goat anti-rat IgG on the nitrocellulose membrane with colloidal gold marked anti-LH-α monoclonal antibody as an mark tracer. The reagent is used to detect the LH in urine according to the principle of double antibody sandwich method and gold immunochromatography assay

Main components

The testing kit is in the form of strip, cassette, and midstream. Basic components: Sample pad, colloidal gold marked pad, nitrocellulose membrane, absorbent paper and PVC board. Colloidal gold marked pad coated with LH-α monoclonal antibody, nitrocellulose membrane coated with LH-β monoclonal antibody，control line coated with goat anti-rat IgG.

Storage and Expiry

Store as packaged in the sealed pouch at 4-30°C, avoid hot and sunshine, dry place, valid for 24 months. DO NOT FREEZE. Some protective measures should be taken in hot summer and cold winter to avoid high temperature or freeze-thaw.

Sample Requirement

A urine sample must be collected in a clean and dry container. A urine sample collected at the same time (10:00 a.m. to 8:00 p.m.) of different day is preferred, however, a first morning urine sample can not be used. Reduce water consumption 2 hours before urine collection to avoid effects on the detection of LH peak, and fresh sample should be used. Urine samples may be stored at 2-8℃ for up to 72 hours prior to assay, and at room temperature for 4 hours. Urine samples exhibiting visible precipitates should be centrifuged, filtered, or allowed to settle to obtain a clear sample for testing..

Test Procedure

Start date of the test: D=A + (B-17)

A is the start date of the last menstrual period; B means menstrual cycle(from the start date of menstrual period to the start date of next menstrual period). If the period is irregular, take the shortest time in the last three months. Generally, the test should be taken for 5 consecutive days.

Instructions must be read entirely before taking the test. Allow the test device controls to equilibrate to room temperature for 30 minutes (20℃-30℃) prior to testing. Do not open the inner packaging until ready, it must be used in one hour if opened (Humidity: 20%~90%, Temp: 10℃-50℃)

Strip:

1. Remove the test device from the sealed pouch, put the end of the test strip print with arrow into the urine, the interface of urine should not exceed the max line, take it out and place the test device on a clean and level surface after 3 to 5 seconds.

2. Observe the test results immediately within 10 minutes, the test result is invalid over 20 minutes.

Cassette:

1. Collect the urine, remove the test device from the sealed pouch, hold the dropper vertically and transfer 2 full drops of urine (approx. 80~100μl) to the sample hole of the test device.

2. Observe the test results immediately within 10 minutes, the test result is invalid over 20 minutes.

Midstream:

1. Remove the test device from the sealed pouch, take out the test kit, remove the cap. Then pour the urine in the absorb stick of test pen directly for 5 to 8 seconds (300 ~400μL.). Notice that the urine should not exceed the market line, cover the cap, flat the test kit onto the table.

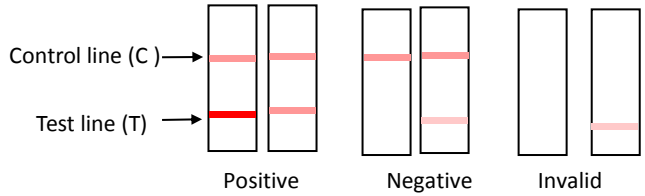
2. Observe the test results immediately within 10 minutes, the test result is invalid over 20 minutes.

Result Judgment

POSITIVE: Two distinct red lines appear. If the color of testing line is stronger than or equal to the control line, it demonstrates that the ovulation is about to occur in the next 24 to 48 hours.

NEGATIVE: One red line appears in the control region(C). Or both red line appear with the color of testing line is weaker than the control line, it demonstrates that the ovulation period does not arrive yet.

INVALID: No red lines appear or control line fails to appear, indicating that the operator error or reagent failure. Verify the test procedure and repeat the test with a new testing device.



Reference Value

The human luteinizing hormone rapid test kit has a sensitivity of 25 mIU/mL.

Interpretation of Results

The reagent only can be used for screening tests, just like all qualitative detection reagents are.

Limitation

1. Concentration of LH cannot be determined by this qualitative test.

2. This reagent is designed for the qualitative screening test. A confirmed diagnosis should be made by other methods.

3. For human urine only. False results may occur when the test is taken in a wrong way.

Performance Characteristics

1. The kit shall meet the following requirements when detected by national standards

1.1 Limit of detection: The limit of detection concentration of the LH colloidal gold reagent is not higher than 25mIU/ml.

1.2 Specificity

1.2.1 The results should be negative of the kits when detected with 200mIU/mL FSH.

1.2.2The results should be positive of the kits when detected with 250mIU/mLTSH.

1.3Repeatability: The results should be consistent and the coloration degree should be consistent when detecting the 25mIU / mL of LH standards by 10 kits of the same batch.

1.4 Lot tolerance: The results should all meet the requirements when detecting the LH liquid of the three different batches.

2 Analytical sensitivity

2.1 Chyluria proteinuria, hematuresis, bilirubinuria and proteinuria has no effect on the detection result,

2.2 The contraceptive pill will cause the luteinizing hormone secretion disorder, easy to cause wrong results. We recommend that women who took contraceptives pill need to stop for 3 months before taking the detection.

Precaution

1. The test device should remain in the sealed pouches until use. If sealing problem happens, do not test. Do not use after the expiration date.

2. Reagents should be used as soon as possible after opened.

3. A number of conditions other than ovulation, including ovarian cyst and, injection or oral administration of LH may affect the detection results.

4. This reagent is designed for the qualitative screening test. A confirmed diagnosis should be made only by a physician after all clinical and laboratory findings have been evaluated.

5. A small bag of desiccant is in the aluminum foil bag, do not eat.

6. All samples and reagents should be considered potentially hazardous and handled in the same manner as an infectious agent after use.