

## (FSH) human Follicular Stimulating Hormone Rapid Test Kit

(Immunochromatography)

### Product Name

(FSH) human Follicular Stimulating Hormone Rapid Test Kit (Immunochromatography)

### Intended Use

The reagent is used to detect the FSH in urine qualitatively. Test results are read visually without the need for any instrument.

### Main Components

The testing kit is in the form of strip and cassette. Basic components: Sample pad, colloidal gold marked pad, nitrocellulose membrane, absorbent paper and PVC board.

### 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. Urine samples may be stored at 2-8°C for up to 48 hours prior to assay. For long-term storage, samples may be frozen and stored below -20°C.

### Test Procedure

Instructions must be read entirely before taking the test. Allow the test device controls to equilibrate to room temperature for 30 minutes (20°C-30°C) 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°C-50°C)

#### 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 seconds.
2. Observe the test results immediately within 10 minutes, the result is invalid over 30 minutes.

#### Cassette:

1. Collect the urine, remove the test device from the sealed pouch, hold the dropper vertically and transfer 3 full drops of urine (approx. 90μl) to the sample hole of the test device.
2. Observe the test results immediately within 15 minutes, the result is invalid over 30 minutes.

#### Midstream:

1. Remove the test device from the sealed pouch, take out the test kit, remove the cap.
2. Then pour the urine in the absorb stick of test pen directly for 5 to 8 seconds. Notice that the urine

should not exceed the mark line. Cover the cap, flat the test kit onto the table.

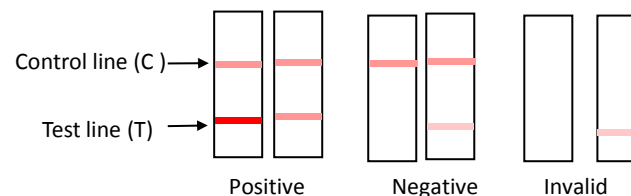
3. Observe the test results immediately within 15 minutes, the result is invalid over 30 minutes.

### Result Judgment

**POSITIVE:** If two color bands are visible and the test band is equal to or darker than the control band, the FSH in the sample is at or above the detection sensitivity of 25 mIU/mL.

**NEGATIVE:** Only one color band appears on the control region or the test band appears but is lighter than the control band. The FSH concentration of the sample is below the detection sensitivity of 25 mIU/mL

**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 follicular stimulating hormone rapid test kit has a sensitivity of 25 mIU/mL.

### Precaution

1. For in vitro diagnostic use only
2. This reagent is designed for the qualitative screening test. A confirmed pregnancy diagnosis should be made only by a physician after all clinical and laboratory findings have been evaluated.
3. Do not use test kit beyond expiry date.
4. The test device should not be reused.
5. Do not use other kinds of quality control sample to test the reagent. Components of different batches cannot be exchanged for use to avoid erroneous results.