



Menopause

(FSH) Rapid Test

INSTRUCTIONS FOR USE

PLEASE READ ALL INFORMATION IN THE INSTRUCTIONS FOR USE BEFORE USING THE TEST!

For over-the-counter (OTC) use.

REF: 01005-1

INTENDED USE

This Suresign™ Menopause (FSH) Rapid Test is intended for *in vitro* qualitative detection of the follicle-stimulating hormone (FSH) level in human urine. Serial urinary FSH testing in combination with key factors such as age and menstrual cycle history may be used to help indicate a woman's menopause stage.

For *in vitro* diagnostic use only. For over-the-counter (OTC) use.

MATERIALS

Material provided

1. One or more pouches each containing a test and a bag of desiccant.
2. Leaflet with instructions for use.

What else do you need?

1. Timer or clock.
2. Urine collection cup

STORAGE CONDITIONS AND SHELF LIFE

1. Store in a dry place at 35.6 ~ 86°F (2 ~ 30°C). **DO NOT** freeze.
2. The shelf life is 24 months. See the product package for the expiration date.
3. Use the test within 1 hour after removing from the foil pouch.

SAMPLE REQUIREMENTS

Collect your urine in a clean, dry urine collection cup, or directly urinate on the absorbent tip of the test. If the urine sample cannot be tested within 2 hours of collection, it can be stored at 35.6 ~ 46°F (2 ~ 8°C) for 2 days. Bring the urine sample to room temperature before testing.

The FSH level in morning urine is the highest. It is recommended to use urine samples collected at the same time every day for testing. Avoid drinking plenty of water and other liquid 2 hours before urine collection.

TAKE THE TEST

The test should be performed at room temperature.

1. Remove the test from foil pouch, take off the cap and use immediately.

Test in urine stream: Hold the test with the absorbent tip pointing downwards into your urine stream (Fig.2). Keep the absorbent tip in the urine stream for **10 seconds**.

Caution: Make sure that only the absorbent tip is wet during sampling and that other parts of the test remain dry.

Or Test in a urine collection cup: Dip the entire absorbent tip into the collected urine for **10 seconds** (Fig.3). **Caution:** Make sure that only the absorbent tip is wet during sampling and that other parts of the test remain dry.

2. After removing the test from your urine, immediately replace the cap, lay it flat with the result window facing upwards, and then begin timing. **Caution:** Never hold the test with

the absorbent tip pointing upwards during testing (Fig.4).

3. Wait a full 10 minutes before reading your result. Do not read the result after 15 minutes.

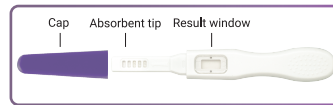


Fig.1 Test



Fig.2 Test in urine stream

Fig.3 Test in a urine container cup



Fig.4 Never hold the test with the absorbent tip pointing upwards during testing.



Fig.5 WAIT 10 mins before checking results. Do not read the result after 15 mins.

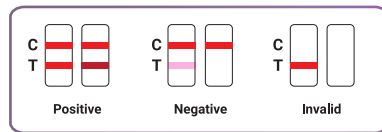
READ YOUR RESULT

FSH levels increase temporarily each month to stimulate your ovaries to produce eggs. A regularly raised level of FSH can be an indication you are approaching or in menopause, when combined with other factors. A confirmed menopause stage diagnosis can only be made by a physician after all clinical and laboratory findings have been evaluated.

Positive: TWO distinct colored lines appear, and the Test line is equal to or darker than the Control line, the test result is positive (See Q1).

Negative: Only ONE colored line appears in the Control Zone (C), or the Test line appears but is lighter than the Control line, the test result is negative (See Q2).

Invalid: No colored line appears in the Control Zone (C), even if a colored line appears in the Test Zone (T), it indicates that the test is invalid (See Q5).



QUESTIONS & ANSWERS

1. My result is Positive. What does this mean?

Your FSH level is at least 25 mIU/mL. If testing during your period, you should avoid testing on days when you are bleeding heavily. To check whether your FSH levels remain high, it is recommended to take a second test 5~7 days after the first test. If you get two or more positive results in serial tests, or if you have any symptoms of menopause, you should see your doctor, who will use your medical history, physical exam, and other laboratory tests to get a more thorough assessment of your condition.

2. My result is Negative. What does this mean?

Your FSH level is lower than 25 mIU/mL. If you have a negative test result, but you have symptoms of menopause, you may be in perimenopause or menopause. You should not assume that a negative test means you have not reached menopause, there could be other reasons for the negative result. You should always discuss your symptoms and your test results with your doctor.

3. Can any medication or conditions affect the results?

The use of any oral contraceptive, patch contraceptives, hormone replacement therapy (HRT), estrogen supplement, or any other hormone may lead to a false negative result in the test. Ovarian and pituitary tumors may lead to incorrect results.

Unclean urine collection cup or improper operation will also produce incorrect results.

4. How does the Suresign™ Menopause (FSH) Rapid Test work?

The FSH test kit detects the hormone FSH (follicle stimulating hormone) in urine to help you find out whether or not you have elevated FSH levels.

5. How do I know that the test was run properly?

The appearance of a colored line in the Control Zone (C) indicates that the test was performed properly. If no colored line appears in the Control Zone (C), even if a colored line appears in the Test Zone (T), it indicates that the test is wrong or invalid. Please make sure that the operation is correct, and retest with a new device.

WARNING AND PRECAUTIONS

1. **DO NOT** make any decision of medical relevance without first consulting your doctor.
2. This product is only for *in vitro* testing of human urine. **NOT** for internal use.
3. This product is for single-use. **DO NOT** reuse.
4. **DO NOT** use the product after the expiration date.
5. The desiccant in the foil pouch is for storage purposes only. **DO NOT** swallow.
6. **DO NOT** use the product if damaged or its pouch is punctured or not well sealed.
7. Keep out of the reach of children.
8. Please follow local regulations to discard used product.

PERFORMANCE CHARACTERISTICS

Accuracy: The overall accuracy of the Menopause (FSH) Rapid Test is over 99%.

Sensitivity: The test detects FSH in urine at a concentration of 25 mIU/mL or greater.

ASSISTANCE



KINGSWAY
PHARMACEUTICALS

Distributed by

Kingsway Pharmaceuticals dba NFI, LLC
636 Shelby Street, Suite 300, Bristol, TN 37620

Questions or Comments?

1.800.432.9334 (Monday to Friday 8:45am - 4:45pm Eastern)

info@kingswaypharma.com US.SURESIGN.COM

MADE IN CHINA

SS-PRD-25-095-IFU