

INTRODUCTION

Follicle Stimulating Hormone (FSH) is produced by the pituitary gland of the brain. During the first phase of the menstrual cycle FSH regulates the growth and development of a mature egg. As a woman approaches menopause the ovaries produce less estrogen and FSH production increases. Over time these hormonal changes cause menstruation to cease completely and “menopause” is said to have occurred. The 2—10 years prior to menopause are called “perimenopause” and during this time levels of FSH may fluctuate affecting fertility and causing irregular or missed periods.

FSH tests can provide useful information for women seeking pregnancy or concerned about ovarian health, function and fertility. For those experiencing irregular menstrual cycles or finding it difficult to conceive FSH tests can help determine if this is related to elevated FSH levels. As FSH levels should normally be below 25 mIU/ml except during mid-cycle, a positive result outside this time indicates that there has been a disruption to the normal menstrual cycle due to the onset of menopause or some other underlying medical condition.

WHEN TO BEGIN TESTING

1. Begin testing on Day 3 of your menstrual cycle - this is the third day of menstrual bleeding.
2. Repeat the test using a new test strip again on Day 4 and 5 of your cycle.

URINE COLLECTION

1. The test can be performed at anytime during the day, however for best results, the urine sample should be collected at the same time each day.
2. It is highly recommended that the first morning urine be tested, since it generally contains the highest concentration of FSH.

TEST PROCEDURE

1. When you are ready to begin testing, open the sealed pouch along the notch. Remove the test from the pouch.



2. Hold the round end of cover in one hand. Use the other hand to remove the cap and expose the absorbent sampler. Put the cap aside now.
3. Point the absorbent tip downwards and place the absorbent tip in the urine stream for at least 10 seconds until thoroughly wet. Alternatively, you can collect urine in a clean cup and dip half of the absorbent pad into the urine for at least 10 seconds. Do not stream past the arrow.



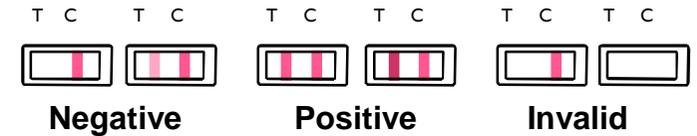
4. Recap the device and wait for coloured bands to appear. Depending on the concentration of FSH, positive results may be observed in as little as 40 seconds. However to confirm negative results, the complete reaction time of 10 minutes is required. It is important that the background is clear before the result is read. Do

INTERPRETATION OF RESULTS

NEGATIVE: Only one pink coloured line appears in the control region (C) or the test (T) line is lighter than the control line. This FSH concentration of the sample is below the detection sensitivity of 25 mIU/ml.

POSITIVE: Two coloured lines appear and the test (T) line is the same colour or darker than the control line (C). The FSH is present in the sample at or above the detection sensitivity of 25 mIU/ml.

INVALID: No visible line at all in the control (C) region. The most likely reason for this is an insufficient volume of urine used or incorrect procedural techniques. Review the testing procedures and repeat with a new test. If the problem persists please contact the supplier.



TEST PRECAUTIONS

1. For in vitro (external) diagnostic use only.
2. To obtain accurate results the directions must be carefully adhered to.
3. Do not use after expiry date on pouch has elapsed.
4. Open sealed pouches only when ready to test.
5. Test strips should not be reused.
6. Keep out of reach of children.

LIMITATIONS

1. As with all diagnostic tests, all results must be considered with other clinical information available to the physician. A definite clinical diagnosis should only be made by a physician after all clinical and laboratory findings have been evaluated.
2. Single measurement of FSH level may give misleading results due to the pulsatile nature of FSH secretion. Samples drawn at different times of the day may vary. Elevated levels of FSH should be confirmed by more than one FSH measurement.
3. The test results should not be affected by pain relievers, antibiotics and other common drugs. Oral contraceptives, hormone replacement therapy and estrogen supplements may affect the test result. As will pregnancy or menopause.
4. A positive FSH test only measures that FSH level is at or greater than 25 mIU/ml (above average) and the transition to menopause is suggested. Menopause by definition is having gone 12 months without a menstrual cycle. A positive FSH test does not give information on exactly when menopause will be reached.
5. If a negative result is obtained while some of the common symptoms associated with menopause are experienced, consult with your physician.
6. A low FSH level may be observed if there is a presence of a tumour in the hypothalamus.

FREQUENTLY ASKED QUESTIONS

1. How accurate is the FSH test?

In both laboratory and consumer clinical studies, the FSH test has been shown to be greater than 99% accurate.

2. How does the FSH test work?

The FSH test strip works by detecting the level of FSH that your body produces in your urine. Usually, as a woman nears menopause her FSH hormone levels rise and surge.

3. Do I have to test with first morning urine?

Although you can use the test any time of the day, your first morning urine specimen is usually the most concentrated of the day and contains the most FSH. For best results try and collect your urine at approximately the same time each day.

4. Will the amount of liquid I drink affect the result?

Heavy intake of fluids before testing will dilute the hormone level in your urine. Limitation of the amount of fluid intake for about two hours before you collect your urine is suggested.

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

The appearance of a red line in the control region of the test tells you that you have followed the test procedure properly and the proper amount of urine was absorbed.

6. What factors may affect the test result?

The test results should not be affected by pain relievers, antibiotics and other common drugs. The test will not work properly if you are pregnant or menopausal. Also, recent oral contraceptive use or breastfeeding can affect results.

7. What should I do if the positive result is observed?

A positive result only measures that FSH level is at or greater than 25mIU (above average) and the transition to menopause is suggested. A positive FSH test does not give information on exactly when menopause will be reached. As with all diagnostic tests, all results should be considered under the clinical supervision of a physician.

FREQUENTLY ASKED QUESTIONS CONTINUED

8. What should I do if the result is negative and I am experiencing some of the common symptoms associated with menopause?

You should consult with your physician.

9. I am close to the age of menopause. My test reads positive but I still have regular periods. Why is this?

A positive FSH test only measures that FSH level is at or greater than 25mIU (above average) and the transition of menopause is suggested. Menopause by definition is having gone for 12 months without a menstrual cycle. A positive FSH test does not give information on exactly when menopause will be reached.

STORAGE

Tests should be stored at temperatures between 4 to 30 C in the sealed pouch to the date of expiration. The test kit should be kept away from direct sunlight, moisture and heat.



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Follicle Stimulating Hormone Test

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