

INTRODUCTION

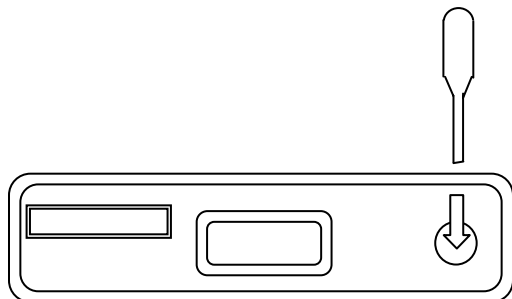
One Step Cassette Style FSH Urine Test is a test kit for the determination of FSH (human Follicular Stimulating Hormone) concentration in urine specimens. Test results are read visually without the need for any instrument.

SPECIMEN COLLECTION & PREPARATION

A urine specimen must be collected in a dry and clean container.

TEST PROCEDURE

1. Remove the test device from its protective pouch (bring the device to room temperature before opening the pouch to avoid condensation of moisture on the membrane). Remove the test from the pouch and use it as soon as possible. Label the device with patient or control identifications.
2. Draw the urine sample using the pipette provided, and dispense 3-4 drops (approx. 0.2ml) onto the sample well of the cassette (see diagram).
3. Wait 10-20 minutes and read result. It is important that the background is clear before the result is read. Do not read results after more than 30 minutes.



PRECAUTION

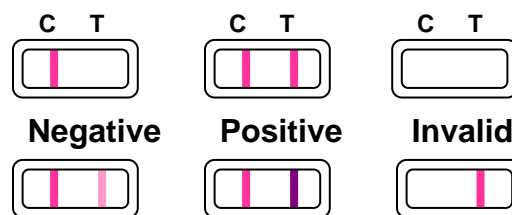
- For in vitro diagnostic use only.
Do not use test kit beyond expiry date.
The test device should not be reused.
4. Keep out of the reach of children.

STORAGE AND STABILITY

The test kit can be stored at temperatures between 2 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.

INTERPRETATION OF RESULTS

- **Negative:** Only one colored band appears on the control (C) region, or the test (T) band appears but is lighter than the control band. This indicates the FSH concentration of the sample is less than 25 mIU/mL.
- **Positive:** Two color bands are visible and the test (T) band is equal to or darker than the control (C) band. This indicates the FSH is present in the sample at or above the detection sensitivity of 25 mIU/mL.
- **Invalid:** No visible band at all or no colored band appears on the control (C) region. A total absence of color in both regions is an indication of procedure error and/or that test reagent deterioration has occurred. Repeat test with a new test kit. If the problem persists, discontinue using the test kit immediately and contact your local distributor.



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 the physician after all clinical and laboratory findings have been evaluated.
2. Single measurement of FSH level may give misleading result 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. After using the pill or patch that contains hCG or LH may affect the test result and should not be taken while using this test kit. In addition, the test will not work properly if you are pregnant or menopausal.
4. A positive FSH test only measures that FSH level is at or greater than 25 mIU/mL (above average) and the transition of 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 given while some of the common symptoms associated with menopause are experienced, consult with the physician.
6. A low FSH level may be observed if there is a presence of a tumor in hypothalamus.

QUESTION & ANSWER

1. Q: How does the test work?
A: The IND One Step Cassette Style FSH Urine Test detects the FSH level in your urine that your body produces. Usually, as a woman near menopause her FSH levels surge and significantly rise.
2. Q: Do I have to test with first morning urine?
A: Although you can use this test kit during any time of the day, your first morning urine specimen is usually the most concentrated of the day and obtains the most hCG in it and that might affect the test result. For best results, try to collect your urine at approximately the same time each day.
3. Q: Will the amount of liquid I drink affect the result?
A: 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.
4. Q: How accurate is the test?
A: In both laboratory and consumer clinical studies, the IND One Step Cassette Style FSH Urine Test has been proved to be greater than 99% accurate.
4. Q: Which factors may affect the test result?
A: The test results should not be affected by pain relievers, antibiotics and other common drugs. After using the pill or patch that contains hCG or LH may give a false positive result and should not be taken while using this test kit. In addition, the test will not work properly if you are pregnant or menopausal. Also, recent oral contraceptive use or breastfeeding can affect the results.
5. Q: What should I do if the positive result is observed?
A: A positive result only measures that FSH level is at or greater than 25mIU/mL (above average) and the transition of menopause is suggested. A positive FSH test does not give information on exactly when menopause will be reached. As all diagnostic tests, all results must be considered with other clinical information available to the physician.
6. Q: How do I know that the test was run properly?
A: The appearance of a red line in the control window (C) tells you that you followed the test procedure properly and the proper amount of urine was absorbed.
7. Q: What should I do if the result is negative while I experienced some of the common symptoms associated with menopause?
A: Consult with your physician as soon as possible.
8. Q: I am close to the age of menopause. My test reads positive but I still have regular periods. Why is this?
A: A positive FSH test only measures that FSH level is at or greater than 25 mIU/mL (above average) and the transition of 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.