

INSTANT-VIEW® One-Step Menopause Midstream Test

In Vitro Diagnostic for external use (not for internal use)
Store At Room Temperature

REAGENTS AND MATERIALS SUPPLIED

Two test devices sealed in a foil pouch with a desiccant pack.

STORAGE

Store the kit at room temperature (15-30°C). Kit contents are stable for at least 2 years or until the expiration date printed on the label, whichever comes first.

Do not freeze the kit as this may cause the device not to work properly. Exposing the kit to temperatures over 30°C may damage or reduce the shelf life of the components. Do not use the device if the foil pouch is broken or if the device has been exposed to air for over 30 minutes.

Do not freeze and/or expose the kit to temperatures over 30°C (86°F).

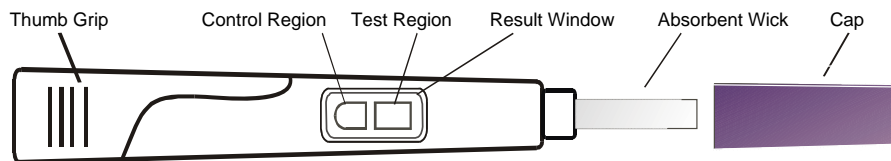


HOW DOES THE TEST WORK?

FSH (follicle-stimulating hormone) is an important hormone that initiates the growth and development of ovarian follicles during the female menstrual cycle. These follicles secrete estradiol, which controls the circulating levels of FSH. At the menopause stage, there is a decrease in estradiol secretion due to the diminished ovarian function and as a result, the FSH levels increase significantly.

The **INSTANT-VIEW®** One-Step Menopause Midstream Test uses antibodies, highly specific to FSH, to detect the presence of FSH in urine. If you obtain a positive result from this test, it indicates that you may reach menopause and you should see your doctor for professional assistance.

THE STRUCTURE OF THE TEST:

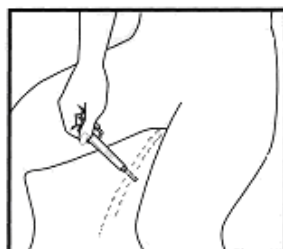


WHEN WOULD BE THE BEST TIME OF DAY TO DO THE TEST?

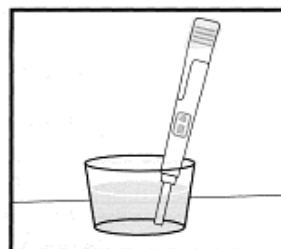
You may perform the test at any time of the day. However, avoid drinking large amounts of liquid for half an hour before testing because the liquid may dilute the FSH in your urine.

HOW TO PERFORM THE TEST

1. Remove the test device from the foil pouch and uncapped the device before testing.
2. **a. Midstream method:** Simply hold the Thumb Grip and place the absorbent wick of the device into your urine stream for about 10 seconds.
b. Optional procedure: If you prefer, you may collect fresh urine in a cup or container, then dip the absorbent wick into the urine. Make sure that at least 4/5 of the wick is submerged into the urine collected. Do not get the plastic body wet. Keep the absorbent wick in the urine for about 10 seconds, and then take it out.
3. Re-cap the test device and place it on a flat surface. Wait for 5 minutes, then read the results displayed in the Result Window.
4. Strong positive results may be evident in 2-3 minutes. Weak positive results may take more time, up to 5 minutes, to become visible. Do not read results after 10 minutes.
5. The above procedure must be followed exactly to obtain correct results. The device cannot be reused.



A. Midstream Method



B. Optional Procedure

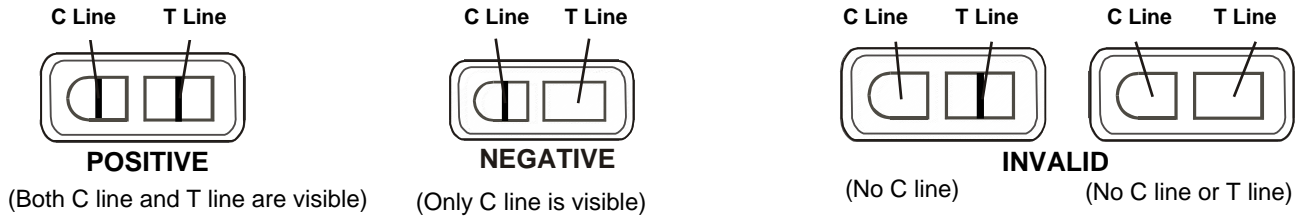
INSTANT-VIEW® One-Step Menopause Midstream Test

HOW TO READ THE RESULTS

POSITIVE: If both C line and T line appear in the viewing window, the test indicates that FSH is detected in the specimen at a level close to or higher than 25 mIU/ml.

NEGATIVE: If only the C line appears, the test indicates that the FSH level in the specimen is not detectable and the result is negative.

INVALID: If no line appears in the control line region, review the procedure carefully and repeat with a new device.



WHAT IS THE FUNCTION OF THE CONTROL LINE?

It is a built-in quality control feature. The appearance of the burgundy C line indicates that the test has been performed correctly. It should always appear regardless of the status of the FSH level. If the control line does not appear within 5 minutes, the result is invalid. In this case, review the section “how to do the test” and repeat test with a new device.

WHY IS THE T LINE VERY FAINT?

The intensity of the T line is related to the concentration of the FSH in the urine. A faint T line indicates a low level of FSH. It is still a positive result.

WHAT IF THE RESULTS ARE NEGATIVE AND SUSPICIOUS?

Repeat the test with a new device and with fresh urine. Follow the procedure exactly. If you still get uncertain results, seek advice from your doctor.

IS THIS TEST RELIABLE?

Yes, in a consumer study, over 95% of the people varying in ages and backgrounds were able to follow the package insert instructions and obtain correct results as confirmed by professionals. This device was also compared to another commercially available pregnancy test in a laboratory study. The accuracy by comparison is greater than 99%.

WHAT ARE THE LIMITATIONS OF THE TEST?

1. This test is not intended for any use other than early detection of Menopause.
2. In certain cases of infertility, treatment with human gonadotropins poses a potential problem for the accurate measurement of FSH. The FSH administered can cause the individual to produce antibodies to FSH, which will interfere directly with the assay results.
3. Positive results must be evaluated with other data by a physician before diagnosis.

DISPOSAL

The *INSTANT-VIEW*® One-Step Menopause Midstream Test does not contain any biohazard material. It may be disposed as regular waste.

ASSISTANCE

Should you have any questions regarding the *INSTANT-VIEW*® Menopause Midstream Test, please call

1(877) 204-5071

Weekdays from 8:30 AM to 5 PM (Pacific Standard Time).