BIOTEST

Your reliable home test kits series

MENOPAUSE TEST KIT

Product Code 9 555223 208043
For In-Vitro Diagnostic and self-testing use
Store at 2-30ºC

INTENDED USE

BioTest Menopause Test is a test kit for the determination of Human Follicle Stimulating Hormone (FSH) concentration in urine specimens. Test results are read visually without the need for any instrument.

PRINCIPLES

Women during fertility age experience regular menstruation cycles (bleeding) as a positive indication of their fertility and normal health conditions. The regularity of these menstruation cycles is maintained by the balance of four hormones, namely Estrogen, Progesterone, Follicle Stimulating Hormone (FSH) and Luteinizing Hormone (LH). Menstruation cycles normally stop during pregnancy but also become less regular (a condition known as perimenopause) and finally stop (a condition known as menopause) with age when the body fails to maintain the balance in the levels of these hormones.

As women age, their bodies fail to retain FSH within its natural normal limits. A characteristic feature of perimenopause is a higher level of FSH than normal. The increase of FSH will occasionally suppress the levels of the other three hormones necessary to cause regular menstruation cycles. This in turn will sometimes lead to short or irregular cycles which signal the start of the perimenopause condition. Eventually, FSH continues to rise causing very low levels of the other three hormones ultimately preventing the menstrual cycle from occurring. This cessation of the menstrual cycle is known as menopause. Since FSH exists in higher levels than normal during perimenopause and menopause, detection of high FSH levels in urine is commonly used as a tool to determine perimenopause and menopause.

The low level of Estrogen during perimenopause and menopause causes many discomforts such as hot flushes, sweating, sleeplessness, depression, palpitations (shivering), degeneration of breasts and genital organs, thinning and dryness of the vaginal epithelium (causing painful intercourse) and in the long run more serious conditions such as heart disease (coronary artery) and decrease in bone structure (osteoporosis) may develop. Many of these symptoms can be reduced by various treatments such as increased calcium intake and hormone replacement therapy. Therefore, early detection of perimenopause and menopause can help women to plan and go through this natural process with minimal discomfort and health risks.

COMPONENTS

- Test Device
- Desiccant
- Instruction for Use

PRECAUTIONS & WARNINGS

- Do not use the test after the expiration date.
- If the package is not completely sealed do not use the test.
- The test should be performed in a well-lit area.
- Use the test device immediately after opening it.
- Do not touch the test window. This could affect results and may also impose personal hazards.
- The pouch contains a desiccant pack to absorb humidity. Do not open the pack. Throw it away with the remaining of the test.
- At the end of the test, wrap everything you have used in a plastic bag and throw away in the pin. Do not forget to wash your hands properly.

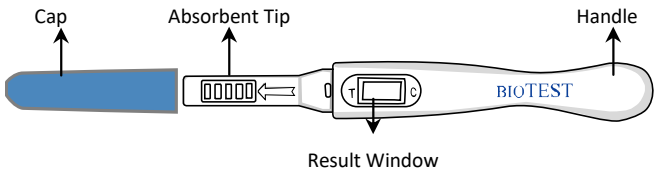
WHEN TO TEST

The first morning urine contains the highest level of FSH and is the best for testing. Urine collected during the day will contain lower levels of FSH and may cause false negatives. Do not drink excess fluids after midnight before testing in the morning. The test can be taken at any time during your cycle and that the second test should be taken 1 week later.

If you are still having menstruation, take the first test during the first week of your cycle (days 2-7, with day 1 being the first day of menstruation). Repeat with the second test one week later.

If you are no longer having regular periods, take the test at any time during the month and repeat with the second test 1 week later.

HOW TO USE THE TEST



1. Read instructions carefully before use.
2. Determine the day you will begin testing (see the above section: When To Test).
3. Check that the test is completely sealed and bring the pouch to room temperature before opening it.
4. Remove the test device from the foil pouch and familiarize yourself with the device.
5. Remove the cap and hold the test by the handle with the exposed absorbent tip pointing downward directly into your urine stream for at least 10 seconds until it is thoroughly wet. Note: Do not urinate on the result window. If you prefer, you can urinate into a clean and dry container, then dip only the absorbent tip of the midstream test into the urine for at least 10 seconds.
6. After removing the test device from your urine stream, immediately replace the cap over the absorbent tip, lay the test on a flat surface with the result window facing upward, and then begin timing.
7. As the test begins to work, you may notice a light red flow moving across the result window. Wait for the red line(s) to appear. Read results in 1 - 5 minutes. It is important that the background is clear before the result is read. Positive results may be observed in 1 to 5 minutes depending on the concentration of FSH. Do not read the result after 10 minutes.

HOW TO READ THE RESULTS

	**Positive:** **2 lines with the (T) line the same or darker than the (C) line.** This indicates that your FSH level is higher than normal and you may be experiencing perimenopause.
	**Negative:** **2 lines with the (T) line lighter than the (C) line or one line in the (C) area.** This indicates that you are probably not experiencing perimenopause in this cycle.
	**INVALID RESULT** **No lines or 1 line in the (T) area.** The result is invalid if the control line (C) fails to develop, even if the test line (T) appears in the result window. The most likely reasons for control line failure are insufficient specimen volume or incorrect procedural techniques. Review the procedure and repeat the test with a new device.

WHAT DOES THE RESULTS MEAN?

For women experiencing menopausal symptoms who have had no menstrual cycle for the past 12 months and get a POSITIVE RESULT.

INTERPRETATION: Menopause has most likely occurred. You may want to repeat the test but discuss the results with your doctor to confirm them and discuss therapies to promote good health after menopause.

For women experiencing perimenopausal symptoms plus irregular menstrual cycles and get a POSITVE and NEGATIVE RESULT using two different tests with the interval of at least of 1 week.
INTERPRETATION: May be in the early stages of perimenopause. Discuss results with your doctor. Do not discontinue contraception.

LIMITATION OF THE TEST

There is the possibility that this test may produce false positive result or false negative results. Consult your physician before making any medical decisions. Invalid results are most likely caused by not following the instructions of use properly. Review the instructions and repeat the test with new test.

QUESTIONS & ANSWERS

Q: How does the test work?

A: As your body ages and produces less estrogen, FSH levels increase as the hormone tries to stimulate the ovaries to produce a healthy egg. This test measures FSH and can tell you whether your body is producing excess FSH as a result of low estrogen levels, signaling that your body is in the perimenopause stage.

Q: When can I use the test?

A: We recommend performing the test using first morning urine as it contains the most hormones and will give the most accurate result. If you are still menstruating, we recommend testing during the first week of your cycle (see WHEN TO TEST) and then retesting one week later.

Q: I received a positive result. Can I stop using contraception?

A: No, this test cannot determine fertility. Continue using contraception until your test results have been confirmed by your doctor.

Q: I am not sure that I held the test in my urine stream long enough. Will I still get an accurate result?

A: In order to receive an accurate result, you should hold the absorbent tip of the test in your urine stream for at least 10 seconds and wait 1-5 minutes to read the result. If the line in the reference window (C) fails to develop, you should repeat with a new test.

Q: How accurate is the test?

A: In laboratory studies, the test was shown to be more than 98% accurate overall.

Q: How sensitive is the test?

A: The Menopause Test can detect FSH at concentrations of 25mIU/mL or greater. The addition of LH (1,000 mIU/mL), hCG (100 IU/mL), and TSH (1,000 IU/mL) to negative (0 mIU/mL FSH) and positive (25 mIU/mL FSH) specimens showed no cross-reactivity.

Q: How will I know the test worked?

A: The appearance of a red line in the reference window (C) tells you that you followed the test procedure properly and the proper amount of urine was absorbed. If you do not see a line in the reference window (C), you should review the procedure and repeat with a new test. The test is not reusable. If you still experience problems, contact your distributor.

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 liquid intake for about two hours before you collect your urine is suggested.

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