

BEFORE PERFORMING THE TEST, PLEASE READ THESE INSTRUCTION CAREFULLY

Menopause TEST

Single use cassette test for determining the level of FSH

Medical device for self-testing

INTRODUCTION

Menopause is the last menstrual period in a woman's life, after which, during 12 monthly cycles, there was no period bleeding. This is an important event in a woman's life, the date of which can be determined after a certain time. It is generally known that the symptoms preceding the menstrual period occur 2-3 years earlier and last a few years after menopause. The whole period is referred to as menopause or climacteric.

In the period preceding menopause, and 12 months after its occurrence (referred to by some as perimenopause), a significant number of women experiences unpleasant symptoms, such as: hot flashes, night sweats, thin and dry skin, joint and bone pain, painful sexual intercourses, recurrent urinary tract infections, incontinence, insomnia, fatigue, depression and irritability, as well as decreased libido.

Menopause is connected with disappearing of reproductive functions – there occurs the expiration of ovarian function, which causes the decreased production of female sex hormones, mainly estrogens. At the same time, a woman's body experiences the increased production of follicle stimulating hormone (FSH). Therefore, the determination of the level of FSH may be helpful in the diagnosis of menopause.

Menopause TEST is a rapid test for the detection of FSH hormone in the urine, with the concentration of 25 mIU/mL, or higher.

Testing is very simple and consists of inserting 3 drops of the urine to the window located on a cassette. Results in the form of coloured lines in a result window are obtained within 5 minutes.

CONTENTS

Packaging of Menopause TEST includes equipment necessary to perform two tests:

- » 2 sealed aluminium bags, each containing: 1 cassette test, 1 pipette and 1 desiccant
- » 1 instruction for use

Prior to testing, prepare a watch that will be necessary to measure a time of reading the test result.

WHEN THE TEST SHALL BE PERFORMED?

» If you are menstruating regularly, but you can observe the symptoms of menopause in your body, then the first test of the packaging shall be used in the first week of the menstrual cycle, i.e. in the period from 2nd to 7th day of your cycle. As a reminder: 1st day of the cycle is the first day of menstrual bleeding. Examination using the second test shall be made exactly one week later.

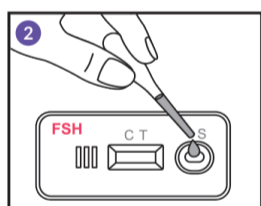
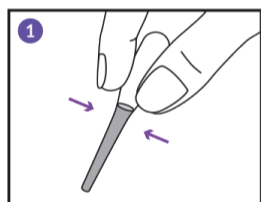
» If you are menstruating irregularly (there occur even longer pauses between periods) and you can observe the symptoms of menopause in your body, then the first test of the packaging shall be performed on any day of the month and the examination shall be repeated with the second test from packaging exactly a week later.

NOTES PRIOR TO TESTING

» The test shall be done using the first morning urine, because it contains the most FSH hormone, and therefore the results will be the most reliable.

» The urine shall be taken to a clean and dry container

» If the test cannot be performed immediately after collecting the urine into the container, then the tested urine can be stored for 48 hours in the refrigerator (in temperature of 2 – 8°C). Do not freeze. » » If the test was stored in temperatures of 2 – 8°C then prior to testing, the container with the urine shall be taken out from the refrigerator and left for half an hour at room temperature.



HOW TO PERFORM TESTING USING THE MENOPAUSE TEST?

» Just before testing, open a foil bag by its tearing. Take out the cassette test and a plastic pipette. The envelope also consists of a desiccant, which shall be discarded with household garbage.

» Place the cassette on a horizontal surface.

» Dip the end of the plastic pipette in the tested urine. Clutching the upper part of the pipette fill it with the urine. ❶

» Dispense slowly **3 full drops** of the urine to the oval window located on the cassette. ❷ To ensure proper performance of the test, the pipette shall be hold upright, about 1 cm above the surface of the cassette, so as to form large, freely-falling drops, without air bubbles.

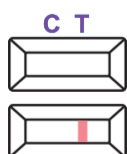
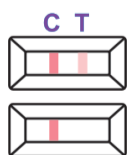
» Observe the movement of the urine sample on an absorbent membrane through a test region and a control region.

» Wait until the result window shows coloured lines

» Read the test result within **5 minutes** after inserting the urine into an oval window located on the cassette. ❸

If you do not see any coloured line, wait 1 minute more.

Do not read the result received after 10 minutes.



HOW TO READ THE MENOPAUSE TEST CASSETTE RESULTS?

POSITIVE RESULT

There are two distinct lines: T (test) and C (control). The intensity of the T line colour is equal or stronger than the intensity of the C line colour. This result indicates that the level of FSH hormone is higher than normal, and you can be in the perimenopause stage.

NEGATIVE RESULT

There occurs the C (control) line, the T (test) line is much weaker or does not appear at all. This result suggests that perhaps the perimenopausal stage will not occur in this cycle.

INVALID RESULT

There is no C (control) line. If the C line does not appear, although the T line occurs, the test result is invalid and the test must be repeated using a new cassette test.

HOW TO INTERPRET THE MENOPAUSE TEST RESULTS?

It relates to women with the menopausal symptoms, who have not had menstruation for the last 12 months.

Test 1	Interprétation
Positive result	Menopause has occurred. You can repeat testing using the second test of the packaging. However, you should contact your doctor to confirm this fact and possibly start the therapy, which is used after menopause.

It relates to women with the menopausal symptoms, who menstruate (regularly or irregularly).

Test 1	Test 2	Interpretacja
Positive result	Positive result	Most likely, you are in the perimenopause stage. Contact your doctor. Do not stop using contraception.
Positive result	Negative result	Most likely, you are in the early perimenopause stage. Contact your doctor. Do not stop using contraception.
Negative result	Positive result	
Negative result	Negative result	Most likely, you are not in the perimenopause stage. If the menopausal symptoms will not be improved, repeat the test in the next month or contact your doctor to discuss other possible causes of your symptoms.

Regardless of the Menopause TEST result (positive or negative) you shall consult your doctor before making any decision.

PRECAUTIONS

- » The test is for external use only.
- » The packaging shall be stored at room temperature of 2-30°C. Do not freeze.
- » Do not use the test after the expiration date shown on the packaging.
- » Do not use the test if the aluminium pouch is damaged, because the moisture in the air could damage the test.
- » Each cassette test in the bag is designed for single use only.
- » The used test shall be disposed as any other household waste.
- » Keep the packaging out of the reach of children.

FREQUENTLY ASKED QUESTIONS

How the Menopause TEST works?

In the case of women in Poland, menopause occurs most often between 45 and 55 years of age. In this time, the production of estrogen and progesterone hormones decreases, while the level of LH and FSH hormones increasing. Principle of the test for menopause is just the use of the increased level of FSH in the urine of a woman during the perimenopause period.

The Menopause TEST is a rapid qualitative test detecting FSH hormone in the urine, with the concentration of 25 mIU/mL, or higher. The principle of the test is based on the antigen-antibody reaction. Anti-FSH antibodies placed on the test membrane during the production process react with FSH hormone present in the urine.

Can I be sure that the Menopause TEST works well?

The occurrence of the C line ensures that the test is working well and the examination has been performed correctly. If the C line does not appear, the test must be performed once again. To do this, use the new test, because each rapid test is designed for single use only.

Can medications affect the Menopause TEST results?

No. However, if you are taking any hormonal medications, then you should consult your doctor. The use of oral contraception, breastfeeding and pregnancy can affect the test result.

I received a positive result of the Menopause TEST. Can I stop using contraception?

No, because the test for menopause is not used to determine fertility. Contraception must be used as long as the positive test result for menopause is not confirmed by a doctor.

How sensitive is the Menopause TEST?

The Menopause Test cassette detects FSH hormone in the urine, with the concentration of 25 mIU/mL, or higher.

How accurate is the Menopause TEST?

Clinical studies show that the accuracy of the Menopause Test cassette is 94%, compared to the EIA tests. The study showed that the Menopause Test cassette is not affected by other hormones present in the urine: LH (up to 300 mIU/mL), hCG (up to 1000 mIU/mL) and TSH (up to 100 IU/mL).







The test result is not affected by the pH of the urine in the range of 5-9 and the following substances: acetaminophen (up to 20 mg/dL), acetylsalicylic acid (up to 20 mg/dL), ampicillin (up to 20 mg/dL), ascorbic acid (up to 20 mg/dL), bilirubin (up to 1 mg/dL), brompheniramine (up to 20 mg/dL), cannabinal (up to 10 mg/dL), caffeine (up to 20 mg/dL), dextromethorphan (up to 20 mg/dL), diphenhydramine (up to 20 mg/dL), ephedrine (up to 10 mg/dL), ethanol (up to 1%), gentisic acid (up to 20 mg/dL), glucose (up to 2 g/dL), hemoglobin (up to 500 mg/dL), ibuprofen (up to 20 mg/dL), ranitidine (up to 20 mg/dL), salicylic acid (up to 20 mg/dL).

Date of the last revision of the instruction: 20.06.2022

Version 6AT/EN

SYMBOLS

CE 1434

	Read the instructions carefully before performing the test		Only for in vitro diagnostics
	For single use only		Store at room temperature 2-30°C
	Lot number		Expiration date



Manufacturer:

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controlly
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