

MenoQUICK®

Menopause Rapid Test

"A new stage in my life. Now?"



INSTRUCTIONS FOR USE

INTRODUCTION

MenoQUICK® is a rapid test for home use and intended for the detection of human Follicle Stimulating Hormone (FSH) in a urine sample. The test helps to assess whether existing symptoms are caused by the climacteric (perimenopause /menopause).

Menopause refers to the time in a woman's life when she stops having a menstrual period. The time leading up to menopause is called perimenopause. Clinically, menopause is defined as the point at which a woman has not had a period in 12 consecutive months. Menopause is a natural physiological process during the life of a woman, which in most cases occurs between the age of 45 and 55. Signs differ between women: some may recognise their menopause from irregular menstruation, which finally stops completely. Others observe changes in their life brought on by symptoms like hot flashes, hair loss, sleep disorders or vaginal dryness. Before the period stops completely, menstrual cycles become irregular in many cases. This often leads to pregnancies in the climacteric, as many women mistakenly believe they are already infertile.

The hormone FSH stimulates growth and maturation of ovarian follicles during the menstrual cycle. In women with a normal, regular cycle the FSH level fluctuates, reaching peak levels of ca. 25 mIU/mL mid-cycle. Menopause is noticeable by the change in sex hormone levels and the resulting symptoms. Since the body produces fewer and fewer estrogens (these hormones trigger ovulation, among other effects), FSH production increases, in order to raise estrogen production in the ovaries. This leads to elevated FSH levels, with an average of approximately 66.5 mIU/ml - 91.6 mIU/ml (Time of the last bleeding / 2 years after the last bleeding) Randolph et al. J Clin Endocrinol Metab 2011;96:746-754.

MenoQUICK® allows you to determine your FSH-concentration to ascertain whether you are in climacteric (the perimenopause or the menopause). You can then take the necessary steps to stay healthy and reduce medical risks which are associated with menopause, such as osteoporosis, hypertension or elevated blood cholesterol.

As an immunochromatographic rapid test **MenoQUICK®** detects the presence of FSH-values over 25 mIU/ml in a urine sample. If the sample contains FSH, it will bind to anti-FSH-antibodies on the test line. Via the interaction with colloidal gold-labelled anti-FSH-antibodies a visible red line is formed (T-line). The test also contains a control system with a control line (C-line).

To determine and interpret the results correctly, it is necessary to carefully read the instructions. All details should be understood before performing the test.

TEST CONTENTS

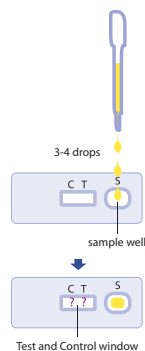
- 2 test cassettes (FSH 25 mIU/ml) with 2 pipettes and desiccant sachet in a sealed pouch
 - 1 instruction pamphlet
- Additionally required:
- 1 Timer
 - 1 Urine collection container

TEST PREPARATION

- To perform the test, please use first morning urine that contains the highest concentration of hormones and gives you the most accurate results.
- If you still get your period, the first test should be performed during the first week of the menstrual cycle (day 2-7, with day 1 as the first day of menstruation). One week later the FSH level should be determined again using the second test device.
- If you do not have a regular menstrual cycle, perform the first test at any time of the month and the second test one week later.

TEST PERFORMANCE

1. Collect your urine in a clean and dry container. The assay should be performed immediately.
2. Remove the test cassette from the foil pouch just before performing the test. Place the device on a clean and level surface.
3. Use the pipette to withdraw urine from the specimen collection container and dispense 3-4 drops in a vertical position into the sample well (S).



Please note, that there should be no liquid applied to the result window marked with the letters (T) and (C). After adding the specimen drops, please do not move the test device.

Read the result 5 minutes after adding 3-4 drops. After more than 10 minutes, false-positive results can occur.

PERFORMANCE EVALUATION

| | | Reference Test | | |
|-----------|----------|----------------|----------|-------|
| | | Positive | Negative | Total |
| MenoQUICK | Positive | 48 | 0 | 48 |
| | Negative | 0 | 444 | 444 |
| | Total | 48 | 444 | 492 |

Sensitivity >99.9 %

Specificity > 99.9 %

Trueness > 99.9%

Accuracy > 99.9 %

EVALUATION OF TEST RESULTS

To read the test results, first determine whether a line is present or absent at the control (C) position. It does not matter how strong or weak the Control line (C) is.

POSITIVE TEST RESULT

For a **positive** result, two red lines appear in the control (C) and test (T) areas of the test window. The intensity of the test line (T) is the same as or stronger than that of the control line (C).



If one or both tests were positive, your symptoms are very likely caused by the climacteric. To get a final diagnosis, consult your physician to discuss further steps.

NEGATIVE TEST RESULT

For a **negative** result, the control line (C) appears in the test window, but the test line (T) is absent or its intensity is less than the control line.



Should both test results be negative but you are experiencing symptoms, they are most likely not caused by the climacteric. In this case diagnostic clarification by your physician is required.

INVALID TEST RESULT

If there is **no control line (C) or only a test line (T)** in the result window, the test did not run correctly and the results are not valid.



It is important that you carefully followed the instructions for the test. You should test again with a new urine sample and a new test.

CROSS-REACTIVITY

The falsification of test results by cross-reactions with various relevant substances can be ruled out. For a complete listing or further questions, please contact the manufacturer.

WARNINGS AND IMPORTANT INFORMATION

- The test is intended for use outside the body only.
- Not to be taken internally.
- Keep out of the reach of children.
- Protect from sunlight, do not freeze. Store in a dry place between 4°C und 30°C.
- Do not use after the expiration date printed on the package.
- Not following the exact instructions can affect the outcome of the test. The final diagnosis must be confirmed by the physician.
- Do not use the test if the packaging is damaged. Do not use broken test components.
- All test components are only intended to be used for this test. Do not reuse the test or test components.
- The test should be carried out immediately or within one hour after opening the foil pouch.
- Poor vision, color blindness or poor lighting may affect your ability to interpret the test correctly.
- All test components can be disposed in household waste.
- Oral contraceptives, hormone replacement therapy or estrogen supplements may affect FSH levels and cause false negative results.
- Ovarian or pituitary tumors may cause false negative results.
- This test must not be used to determine fertility. Contraception decisions should not be made based on test results.

Explanation of symbols:

| | | |
|------------------------------------|---|--------------------------------------|
| Follow instructions | In vitro diagnostic medical device (for external use) | Best before (See imprint on package) |
| Store at 4°C - 30°C Do not freeze! | Content sufficient for 2 tests | Do not reuse |
| Manufacturer | Catalogue number | Batchnumber (See imprint on package) |

CE 0483

REF 300000

Instructions English
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NanoRepro
For the love of life.