

MySet™ Menopause

A home test for the detection of follicle stimulating hormone (FSH)

INSTRUCTIONS

Rapid, easy-to-use, and reliable home test for the detection of follicle stimulating hormone (FSH) in urine.

- Contents:
- 2 tests
 - 2 sampling sticks
 - Instructions for Use

Introduction

In a woman's life moving from the fertile age into non-fertile age involves many changes. During this time the following symptoms can occur: period failures, irregular cycle, hot flashes, sleeplessness, headache, pain, nervousness and feeling of depression. Often the reason for these symptoms is changes in hormone balance. The body has decreased the production of estrogen and progesterone and this has caused increased production of FSH (follicle stimulating hormone).

Usually menopause will start between the ages of 46-56. The start depends on many reasons. Stress, smoking and being underweight are related to early menopause. Menopause has started when the level of FSH reaches the constant and increased level > 25 mIU/ml.

MySet™ Menopause test detects FSH hormone in urine. With this test you can find a reason for unexplained symptoms. The test result is indicative for menopause and you should consult your doctor for treatment.

Perform the test in a well illuminated place according to the instructions for use. Besides the test you need only a watch for timekeeping.

Notes

- ❖ Positive test results should be confirmed by performing the a new test after 7 days
- ❖ Do not take the test out of the box until ready to use
- ❖ Do not use after the expiration date printed on the package or if the foil pouch has been damaged
- ❖ The test is for in vitro diagnostic use only (not for internal use)
- ❖ Hormonal treatment affects the FSH concentration. Hormone replacement therapy decreases the FSH level and thus may give negative results
- ❖ Use each test device only once
- ❖ No diagnosis or decisions concerning treatment shall be made solely on the basis of test results.

If the result is contrary to your expectations, contact your gynecologist.

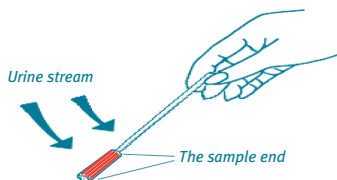
Specimen collection

Use of morning urine is not required, but for best results, test at about same time each day. Try not to drink liquids for 2 hours before testing.

Test procedure

1 Open the pouch protecting the MySet™ Menopause test just before use. Remove the test from the pouch. The test consists of the **test device** (with one window for the test and control lines and a sample well) and a **sampling stick** that contains the test reagent.

2 Collect the sample by placing the wider sample end of the sampling stick under the urine stream for a few seconds.



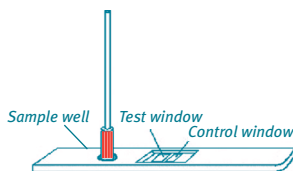
NOTE!

The urine sample should be collected on the **sample stick only** by placing the stick in the urine stream. **Do not immerse** the stick in the urine sample if collected in any vial.

3 Withdraw the sampling stick from the urine stream and keep the sample end of the stick pointing down for a few seconds and shake once to remove extra drops of urine. **Do not turn the sample end of the test stick up at any time.**

4 Place the Sampling stick in the sample well on the device. **Make sure the sampling stick touches the bottom of the well.**

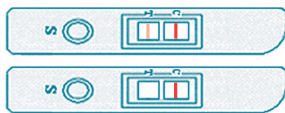
5 Place the device on a flat surface with the window side up. Make sure that the test reagent starts to migrate. If this does not happen within a couple of minutes make sure the sampling stick is pressed all the way in the sampling well. If needed, add more sample to the test stick. **Read the result 10 minutes later** after having placed the device on a flat surface in a well-illuminated place.



Interpretation of the test result

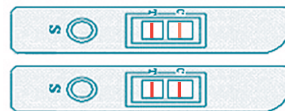
Interpret the result by comparing the intensity of the red color in the test and control lines (do not compare the width of the lines).

FSH LEVEL NOT INCREASED



In case the test line is weaker (less intensely red) than the control line or if it is absent, your FSH level has not increased.

INCREASED FSH LEVEL



If the test line is more intensely colored than the control line or if it is equally as red as the control line, your FSH level has increased.

If you get a positive result, you should repeat the testing after seven days with a new test device. If the result of the second testing is positive, the FSH level is constantly over 25 mIU/ml.

If the first result is positive but a second result is negative, it is probable that your menopause has not yet started and the positive result was obtained at the time of ovulation, where there is a peak in your FSH level.

If the control line does not form, you have likely not followed the instructions for use, or the test unit has been damaged. In such a case repeat the testing with a new test unit.

Stability and storage

The test should be stored unopened until used. Store at room temperature (59-86°F). The expiration date is on the test package and the pouch. Do not use after the expiration date. After opening the pouch, the test should be used within 10 minutes.

Frequently Asked Questions

Q. What could interfere with my test results?

A: Alcohol, pain killers, etc. do not affect on the test result. There are a few medical cases which can result in abnormal FSH levels such as disorders of the hypothalamus or pituitary gland. Therefore if the test result is contrary to expectation, please contact your doctor.

Q. What if no line appears in either window?

A. If you do not see a line in the control window, the test is invalid and must be repeated by performing a new test. Call Customer Support with any questions.

Q. What if I am unsure of my test result?

A. The built-in control line means that you did the test right. If you do not see a control line, the test did not work. Make sure you follow all instructions carefully. To confirm your FSH test you should repeat the testing after 7 days. The line in the test window should be as dark as or darker than the control line. If you have questions about your results call the Customer Support line.

Q. How accurate is the MySet Menopause Test?

A. The accuracy of the test is 99% when compared to similar products.

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Pat. pend. US2005/0181521A1

Customer support: 866-730-5158

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