Menopause Test

FSH Rapid Test Midstream

CE 0123 REF FFS-103H ENGLISH

A rapid test for the qualitative detection of follicle-stimulating hormone (FSH) in human urine sample. For self-testing *in vitro* diagnostic use only.

INTENDED USE
The Menopause Test (FSH Rapid Test Midstream) is a rapid chromatographic immunoassay for the qualitative detection of follicle stimulating hormone (FSH) in urine to evaluate the onset of menopause in women.

SUMMARY AND PRINCIPLE
Menopause is the permanent cessation of menstruation but is usually not scientifically diagnosed until one full year after a woman's menstrual periods have stopped. The period leading up to menopause, and the 12 months following, is known as perimenopause. Many women experience symptoms during this time including hot flushes, irregular menstrual cycles, sleep disorders, vaginal dryness, hair loss, anxiety and mood swings, short-term memory loss and fatigue. The onset of perimenopause is caused by changes in the levels of hormones in the female body that regulate the menstrual cycle. As the body produces less and less oestrogen, it increases its production of follicle-stimulating hormone (FSH), which normally regulates the development of a female's eggs.[1-3]

Therefore, testing for FSH can help determine whether a woman is in the perimenopause stage. If a woman knows she is perimenopausal, she can take the appropriate steps to keep her body healthy and avoid the health risks associated with menopause, which include osteoporosis, increased blood pressure and cholesterol, and increased risk of heart disease.[4,5]
The Menopause Test (FSH rapid test midstream) is a rapid, one-step lateral flow immunoassay for the qualitative detection of FSH in urine to aid in the detection of menopause. The test utilises a combination of antibodies including monoclonal anti-FSH antibodies to selectively detect elevated levels of FSH. The assay is conducted by urinating on or immersing the absorbent tip of the test in urine, and obtaining the result from the coloured lines.

REAGENT
The test contains anti-FSH particles and anti-FSH antibodies coated on the membrane.

PRECAUTIONS
Please read all the information in the instructions for use before performing the test.
- Do not use after the expiration date.
- The test should remain in the sealed pouch until use.
- Store in a dry place at 2-30°C(36-86°F). Do not freeze.
- Do not use if pouch is torn or damaged.
- Keep out of the reach of children.
- For *in vitro* diagnostic use only.
- Do not open the foil pouch until you are ready to start the test.
- Use the test only once.
- The used test should be discarded according to local regulations.

STORAGE AND STABILITY
Store as packaged at room temperature or refrigerated (2-30°C). The test is stable until the expiration date printed on the sealed pouch. The test must remain in the sealed pouch until use. Do not freeze. Do not use after the expiration date.

SPECIMEN COLLECTION AND PREPARATION
The urine specimen must be collected in a clean and dry container. First morning urine specimen is preferred since it generally contains the highest concentration of FSH; however, urine specimens collected at any time of the day may be used. Urine specimens exhibiting visible precipitates should be centrifuged, filtered or allowed to settle to obtain a clear specimen for testing.

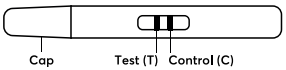
SPECIMEN STORAGE
Urine specimens may be stored at 2-8 °C for up to 48 hours prior to testing. For prolonged storage, specimens may be frozen and stored below -20°C. Frozen specimens should be thawed and mixed before testing.

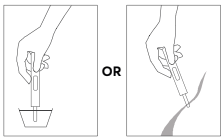
MATERIALS PROVIDED
- Midstream test
- Instructions for use
- Product summary

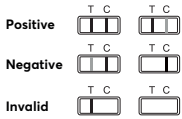
MATERIALS NOT PROVIDED
- Timer
- Specimen containers

INSTRUCTIONS
WHEN TO START TESTING
- If you are still having monthly periods, take the first test during the first week of your cycle (days 2-7, with day 1 being the first day of menstruation). If the result is negative but symptoms persist, 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.

DIRECTIONS FOR USE
Allow the test and urine specimen to reach room temperature (15-30°C) prior to testing.
1. Determine the day to begin testing (See the above section: "WHEN TO START TESTING").
2. Remove the test from the sealed pouch and use within one hour.
3. Remove the cap of the midstream and hold the absorbent tip in the urine stream, or place the absorbent tip (≥2/3) in to the urine sample in a clean cup for at least 10-15 seconds.
4. Replace the cap on the midstream test, then place the product on a flat, clean surface with the test and control window facing upwards, and start the timer.
5. Read the results at 3 minutes. Do not interpret the results after 10 minutes.







READING THE RESULTS
(Please refer to the illustration above)
POSITIVE: Two lines are visible and the line in test line region (T) is the same as or darker than the line in the control line region (C).
A positive result means that the FSH level is higher than normal. Record the results and see the chart above to interpret results.

NEGATIVE: Two lines are visible, but the line in the test line region (T) is lighter than the line in the control line region (C), or there is no line in the test line region (T). A negative result means that the FSH level is not elevated at this time. Record the results and see the chart above to interpret results.

INVALID: Control line fails to appear. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test with a new test. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

TEST INTERPRETATION
For females experiencing perimenopausal symptoms along with irregular menstrual cycles:

1st test	2nd test	Interpretation
Positive	**Positive**	Most likely in perimenopause. Discuss methods and therapies to promote good health after menopause with doctor. DO NOT immediately discontinue contraception.
Positive	**Negative**	May be in early stages of perimenopause. DO NOT immediately discontinue contraception.

OR

Negative	**Positive**	May be in early stages of perimenopause. DO NOT immediately discontinue contraception.
Negative	**Negative**	Most likely not experiencing perimenopause this cycle. If symptoms persist, repeat testing in the following month or review other possible causes for symptoms.

For female experiencing menopausal symptoms with NO menstrual cycle for the past 12 months:

1st test	Interpretation
Positive	Menopause has most likely occurred. Test may be repeated. Discuss methods and therapies to promote good health after menopause with doctor.

CONTROL PROCEDURE
A procedural control is included in the test. A coloured line appearing in the control line region (C) is an internal procedural control. It confirms sufficient specimen volume, adequate membrane wicking and correct procedural technique.

LIMITATIONS
There is the possibility that this test may produce false positive or false negative results. Consult your physician before making any medical decisions. Invalid results are most likely caused by not following the instructions properly. Review the instructions and repeat the test with a new test. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

FAQs
1. Q: How does the test work?
A: As your body ages and produces less oestrogen, 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 oestrogen levels, signalling that your body is in the perimenopause stage.
2. Q: When can I use the test?
A: We recommend performing the test using first morning urine as it contains the most hormone 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 START TESTING) and then retesting one week later.
3. Q: How will I know the test worked?
A: The appearance of a coloured line in the control window (C) tells you that you followed the test procedure correctly and the proper amount of urine was absorbed. If you do not see a line in the control window (C), you should review the procedure and repeat with a new midstream test. The test is not reusable. If you still experience problems, contact your distributor.
4. Q: I received a positive result. Can I stop using contraception?
A: No, this test cannot determine fertility. Continue using contraception until your menopause status has been confirmed by your doctor.
5. 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 urine stream for at least 10-15 seconds and wait 3 minutes to read the result. If the line in the control window (C) fails to develop, you should repeat with a new midstream test.
6. Q: How accurate is the test?
A: A clinical evaluation was conducted comparing the results obtained using the Menopause Test (FSH rapid test midstream) to another commercially available urine FSH test. The clinical trial included 250 urine specimens: both assays identified 85 positive and 165 negative results. The results demonstrated 100.0% overall accuracy of The Menopause Test (FSH rapid test midstream) when compared to the other urine FSH test.
7. Q: How sensitive is the test?
A: The Menopause Test (FSH rapid test midstream) detects follicle-stimulating hormone (FSH) in urine at concentrations of 25 mIU/mL or higher. The addition of LH (1,000 mIU/mL), hCG (100 mIU/mL), and TSH (1,000 µIU/mL) to negative (0 mIU/mL FSH) and positive (25 mIU/mL FSH) specimens showed no cross-reactivity.
8. Q: Do alcohol or common medications affect the test?
A: No, but you should consult your physician if you are taking any hormonal medication. Also, recent oral contraceptive use, breastfeeding, or pregnancy or any intake that can alter the hormonal balance can affect the test results.

BIBLIOGRAPHY

1. Turkington CA.The Perimenopause Sourcebook.Contemporary Books, New York, NY. 1998.
2. Perry S, O'HanlanK. Natural Menopause: The Complete Guide. Reading, MA, Addison-Wesley, 1997.
3. Stanford, JL, WeissNS,etal. Combined Estrogen and Progestin Hormone Replacement Therapy in Relation to Risk of Breast Cancer, J.Am.Med Assoc.1995;274(2):137-142.
4. SperoffL, GlassRH, KaseNG, Clinical Gynecologic Endocrinology and Infertility 5th Ed, Williams and Wilkins, Baltimore, MD.1994; 588.
5. Jacobs DS, Demott DR, Grady HJ, Horvat RT, Huestis DW, Kasten BL, Laboratory Test Handbook 4thEd, Lippincott Williams and Wilkins, Baltimore, MD.1996

Index of Symbols

	Manufacturer		Tests per kit	EC REP	Authorised Representative in EU
IVD	For *in vitro* diagnostic use only		Use by		Do not reuse
	Store between 2-30°C	LOT	Lot Number	REF	Catalogue #
	Do not use if package is damaged		Do not use if package is damaged		Non-recyclable
	Pap 21 recyclable material		Pap 22 recyclable material		

CE 0123

EC REP
MedNet EC-REP GmbH
Borkstrasse 10,
48163 Muenster,
Germany

Number: 146731202
Revision date: 2023-01-29