

FSH Rapid Test Midstream (Urine) Package Insert

A rapid test for the qualitative detection of follicle stimulating hormone (FSH) in urine. For professional *in vitro* diagnostic use only.

【INTENDED USE】

The FSH Rapid Test Midstream (Urine) is a rapid chromatographic immunoassay for the qualitative detection of follicle stimulating hormone (FSH) in urine to aid in the detection of menopause.

【SUMMARY】

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 flashes, 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 estrogen, it increases its production of 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 FSH Rapid Test Midstream is a rapid test that qualitatively detects the FSH level in urine specimen at the sensitivity of 25 mIU/mL. The test utilizes a combination of antibodies including a monoclonal anti-FSH antibody to selectively detect elevated levels of FSH.

【PRINCIPLE】

The FSH Rapid Test is a qualitative, lateral flow immunoassay for the qualitative detection of human Follicle Stimulating Hormone in urine to evaluate the onset of menopause in women. The test utilizes a combination of antibodies including a monoclonal anti-FSH antibody to selectively detect elevated levels of FSH. The assay is conducted by urinate on or immersing the test midstream in a urine specimen and observing the formation of colored lines.

The specimen migrates via capillary action along the membrane to react with the colored conjugate. FSH present in the specimen binds to the conjugate, forming a colored antibody-antigen complex. The FSH antibody immobilized in the test zone of the membrane captures the FSH-Conjugate (antibody + signal reagent) complex in the test region and the rabbit antibody immobilized in the control zone of the membrane captures the conjugate in the control region. Two lines are thus visible. If the line in test line region is same as or darker than the line in the control line region, it indicates a positive result. If the line in the test line region is lighter than the line in the control line region; or if there is no line in the test line region, it indicates a negative result. To serve as a procedural control, a colored line will always appear in the control line region, indicating that proper volume of specimen has been added and membrane wicking has occurred.

【REAGENT】

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

【PRECAUTIONS】

- For professional *in vitro* diagnostic use only. Do not use after expiration date.
- The test should remain in the sealed pouch until use. Do not use the test if pouch is damaged.
- Do not eat, drink or smoke in the area where the specimens or kits are handled.
- Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout the procedure and follow the standard procedures for proper disposal of specimens.
- Humidity and temperature can adversely affect results.

【STORAGE AND STABILITY】

Store as packaged at room temperature or refrigerated (2-30°C). The test is stable through the expiration date printed on the sealed pouch. The test must remain in the sealed pouch until use. **DO NOT FREEZE.** Do not use beyond the expiration date.

【SPECIMEN COLLECTION AND PREPARATION】

The urine specimen must be collected in a clean and dry container. A 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】

Materials provided	• Package Insert
Materials required but not provided	• Timer
Specimen collection containers	

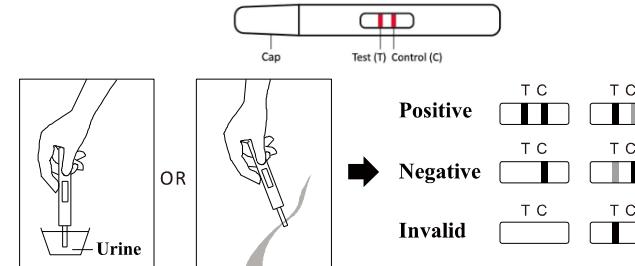
【WHEN TO START TESTING】

- If the subject is still having monthly periods, then the first test should be taken during the first week of her menstrual cycle (Days 2-7, with Day 1 being the first day of menstruation). Repeat with the second test 1 week later.
- If the subject is no longer having regular periods, the first test should be taken at any time during the month and the second test should be taken 1 week later.

【DIRECTIONS FOR USE】

Allow the test, urine specimen and/or controls to reach room temperature (15-30°C) prior to testing.

- Determine the day to begin testing. (See the above section: "WHEN TO START TESTING".)
- Bring the pouch to room temperature before opening it. Remove the test midstream from the sealed pouch and use it as soon as possible.
- Take down the cap of the midstream, then urinate on it or place the **absorbent tip**(2/3) into urine sample in a clean cup at least **15 seconds**(see illustration below).
- Cover the cap on the testing midstream, then lay down the product on a clean and stable desk with the test and control window face upwards, and then start the timer immediately.
- As the test begins to work, you may notice a light colored flow moving across the test and control window. **Read the result at 3 minutes.** Do not interpret the result after 10 minutes.



【INTERPRETATION OF RESULTS】

(Please refer to the illustration)

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 below 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 below 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】

Review the results of both tests (if applicable) and interpret according to the chart below.

For patients experiencing premenopausal symptoms plus irregular menstrual cycles:

1st Test	2nd Test	Interpretation
Positive	Positive	Most likely in perimenopause. Discuss with patient methods and therapies to promote good health after menopause. Patient should NOT immediately discontinue contraception.
Positive	Negative	May be in early stages of perimenopause. Patient should NOT immediately discontinue contraception.
OR		
Negative	Positive	Most likely not experiencing perimenopause this cycle. If symptoms persist, repeat patient testing in the following month or review other possible causes for symptoms.
Negative	Negative	Most likely not experiencing perimenopause this cycle. If symptoms persist, repeat patient testing in the following month or review other possible causes for symptoms.

For patients experiencing menopausal symptoms who have had NO menstrual cycle for the past 12 months:

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

【QUALITY CONTROL】

A procedural control is included in the test. A colored 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.

It is recommended that external positive and negative controls be tested with each new kit, lot or shipment of product, with each change in operator within the test kit,

weekly as a check on continued storage conditions, and as otherwise required by your laboratory's internal quality system procedures.

【LIMITATIONS】

- The test works only when the test procedures are precisely followed.
- Do not reuse the test device.
- For professional *in vitro* diagnostic use only.
- Oral contraceptive and pregnancy may affect the test and produce inaccurate results.
- The test may not be used to determine fertility. It cannot be used to determine the ability to become pregnant. Contraception decisions should not be made based on the results of this test alone.
- Keep out of the reach of children.

【PERFORMANCE CHARACTERISTICS】

Accuracy

A multi-center clinical evaluation was conducted comparing results obtained using the FSH Rapid Test to another commercially available urine membrane FSH test. The results of the study, which included 250 urine specimens, demonstrated 100.0% accuracy of the FSH Rapid Test when compared to the other urine FSH test.

FSH Rapid Test vs. Other FSH Rapid Test

Method	Other FSH Rapid Test		Total Results
	Results	Positive	
FSH Rapid Test	Positive	85	85
	Negative	0	165
Total Results		85	165
250			

Positive Agreement: 100.0% (96.6%-100.0%)*

Negative Agreement: 100% (95.7%-99.9%)*

Overall Agreement: 100% (97.1%-99.9%)*

*95% Confidence Interval

Sensitivity and Specificity

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

Interfering Substances

The following potentially interfering substances were added to FSH negative and positive specimens.

Acetaminophen: 20 mg/dL

Caffeine: 20 mg/dL

Acetylsalicylic Acid: 20 mg/dL

Gentisic Acid: 20 mg/dL

Ascorbic Acid: 20 mg/dL

Glucose: 2 g/dL

Acetoacetic Acid: 2 g/dL

Hemoglobin: 500 mg/dL

Bilirubin: 100 mg/dL

None of the substances at the concentrations tested interfered in the assay.

BIBLIOGRAPHY

- Turkington CA. The Perimenopause Sourcebook. Contemporary Books, New York, NY. 1998.
- Perry S, O'Hanlan K. Natural Menopause: The Complete Guide. Reading, MA, Addison-Wesley, 1997.
- Stanford, JL, Weiss NS, et al. Combined Estrogen and Progestin Hormone Replacement Therapy in Relation to Risk of Breast Cancer, *J. Am. Med. Assoc.* 1995; 274(2): 137-142.
- Speroff L, Glass RH, Kase NG. Clinical Gynecologic Endocrinology and Infertility 5th Ed, Williams and Wilkins, Baltimore, MD. 1994; 588.
- Jacobs DS, Demott DR, Grady HJ, Horvat RT, Huestis DW, Kasten BL, *Laboratory Test Handbook* 4th Ed, Lippincott Williams and Wilkins, Baltimore, MD. 1996.

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