Suresign Menopause (FSH) Rapid Test Midstream (Urine)
Package Insert
For Self-testing

REF FFS-103H	English

A rapid test for the qualitative detection of Follicle-Stimulating Hormone (FSH) in urine sample.
For self-testing in vitro diagnostic use only.

【INTENDED USE】
The Suresign Menopause (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 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 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 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 Suresign Menopause (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 contains anti-FSH particles and anti-FSH coated on the membrane and utilizes 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 test midstream in urine and obtaining the result from the coloured lines.

【PRECAUTIONS】
Please read all the information in this package insert before performing the test.
- For self-testing *in vitro* diagnostic use only.
- For external use only
- Do not use after the expiration date
- Do not open the foil pouch until you are ready to start the test.
- Store in a dry place at 2-30°C (35.6-86°F).
- Do not freeze
- Do not use if pouch is torn or damaged.
- Keep out of the reach of children.
- Use the test only once.
- The used test should be discarded according to local regulation

【STORAGE AND STABILITY】
Store as packaged at room temperature or refrigerated 2-30°C (35.6-86°F). 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.

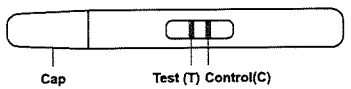
【SPECIMEN STORAGE】
Urine specimens may be stored at 2-8°C (35.6-46.4°F), for up to 48 hours prior to testing.

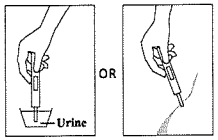
【MATERIALS PROVIDED】
- Test Midstream (2 or more tests)
- Package insert

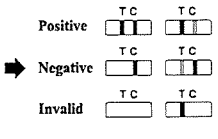
【MATERIALS REQUIRED BUT NOT PROVIDED】
- Timer
- Specimen containers

【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, urine specimen and/or controls to reach room temperature 15-30°C (59-86°F) prior to testing.
1. Determine the day to begin testing. (See the above section: "WHEN TO START TESTING").
2. Bring the pouch to room temperature before opening it. Remove the test from the sealed pouch and use immediately.
3. Remove the cap from the test and hold the test so as to place all of the absorbent tip in the urine stream for at least **10 seconds** or place the absorbent tip into the urine sample in a clean cup for at least **10 seconds.** If you are unsure of the contact time, use the cup/dip method and a timer. **Note: DO NOT ALLOW URINE PASSED THE ARROW OR TO FLOOD THE TEST WINDOW.**
4. Replace the cap on the test, place the test on a clean level surface with the **Test(T)** and **Control (C)** line window facing upwards, then start the timer immediately.
5. As the test begins to work, you may notice a light-coloured flow moving across the **Test (T)** and **Control (C)** line window, this is normal. **Read the result at 3 minutes.** Do not interpret the result 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 result and see the **TEST INTERPRETATION** section below to interpret the 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 result and see the **TEST INTERPRETATION** section below to interpret the results.

INVALID: Control line (C) fails to appear even if the Test Line(T) appears. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for **Control line (C)** failure. Review the procedure and repeat the test with a new test. If the problem persists, discontinue using the test kit immediately.

TEST INTERPRETATION
For female 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 your doctor. DO NOT immediately discontinue contraception.
Positive	Negative	May be in early stages of perimenopause. DO NOT immediately discontinue contraception.
OR		
Negative	Positive	
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 your 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 Doctor 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.

【USEFUL INFORMATIONS】
1. **Q: How does the test work?**
   A: As your body ages and produces less estrogen, 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 estrogen levels, signaling 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 TEST) 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 properly 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.
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 Suresign Menopause (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 Suresign Menopause (FSH) Rapid Test Midstream when compared to the other urine FSH test.
7. **Q: How sensitive is the test?**
   A: Suresign Menopause (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 (100mIU/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 doctor 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】

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3. 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.
4. Speroff L, Glass RH, Kase NG, 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 4th Ed, Lippincott Williams and Wilkins, Baltimore, MD. 1996

Index of Symbols

	Manufacturer	Σ	Tests per kit	EC REP	Authorized Representative
IVD	For in vitro diagnostic use only		Use by		Do not reuse
	Store between 2-30°C (35.6-86°F)	LOT	Lot Number	REF	Catalog #
	Do not use if package is damaged		Consult Instructions for Use		

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