FSH One Step Menopause Test Midstream

Package Insert

Catalogue number:	FSH-103	Specimen:	Urine
Version:	B	Effective Date:	2022-09-26

For self-testing

【INTENDED USE】

TThe FSH One Step Menopause Test Midstream is a rapid lateral flow chromatographic immunoassay for the qualitative detection of Follicle-Stimulating Hormone (FSH) level in urine to evaluate the onset of menopause in women. For self-testing and in vitro diagnostic use only.

【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, 2, 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 One Step Menopause 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. At the level of claimed sensitivity, The FSH One Step Menopause Test Midstream shows no cross-reactivity interference from the structurally related glycoprotein hormones hCG, hLH and hTSH at high physiological levels.

【PRINCIPLE】

The FSH One Step Menopause Test Midstream 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 adding a urine specimen to the specimen well of the test device and observing the formation of colored lines. The specimen migrates via capillary action along the membrane to react with the colored conjugate.

Positive specimens react with the specific antibody-FSH-colored conjugate to form a colored line at the test line region of the membrane. Absence of this colored line suggests a negative result. To serve as a procedural control, a colored line will always appear in the control line region, indicating that the proper volume of specimen has been added and membrane wicking has occurred.

【REAGENTS】

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

【PRECAUTIONS】

- For Self Testing. Do not use after the expiration date.
- The test should remain in the sealed pouch until use.
- Do not use test if pouch is damaged.
- All specimens should be considered potentially hazardous and handled in the same manner as an infectious agent.
- The used test should be discarded according to local regulations.
- Do not swallow, keep away from children.
- DO NOT RE-USE test midstream.

【STORAGE AND STABILITY】

Store as packaged in the sealed pouch either 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. Ensure that a sufficient quantity of the specimen is collected to allow submerging the dipping area of the device.

【KIT CONTENTS】

● Test Midstream(s)	● Package insert	● Desiccant(s)

【KIT CONTENTS】（optional）

- Specimen collection container(s) (for specimens collection use)

【MATERIALS REQUIRED BUT NOT PROVIDED】

- Timer (for timing use)

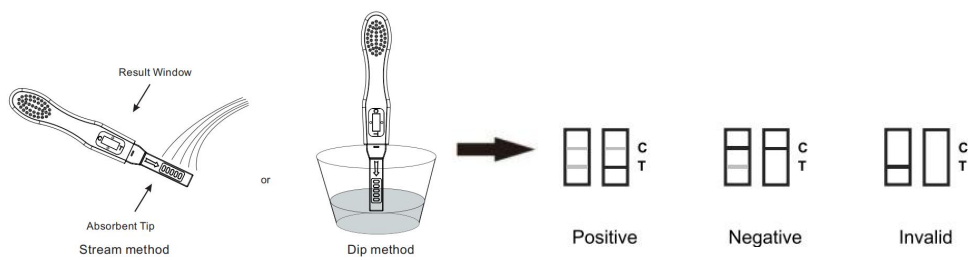
【WHEN TO TEST】

- 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.

【INSTRUCTIONS】

Remove the test from its sealed pouch and use it as soon as possible. To obtain a best result, the assay should be performed within one hour.

1. Remove the midstream test from the foil pouch and familiarize yourself with the product.
2. Hold the midstream test by the Thumb Grip with the **Absorbent tip pointing downward directly into your urine stream for 5-10 seconds**. See illustration below.
3. **NOTE: Do not urinate on the Result window.** If you prefer, you can urinate into a clean and dry container, then dip only the Absorbent tip of the midstream test into the urine for at least 10-15 seconds. Do not pass the arrow on the midstream when dipping the midstream into the urine.
4. After removing the midstream test from your urine, immediately lay the midstream test on a flat surface with the Result window facing upwards, and then begin timing.
5. As the test begins to work, you may notice a light colored flow moving across the Result window. **Read the result at 5 minutes.**Do not read the result after 10 minutes.



【READING THE RESULTS】

(Please refer to the illustration above)

POSITIVE: Two distinct colored lines are visible, and the line in the test line region (T) is the same as or

darker than the line in the control line region (C). A positive result indicates that the FSH level is higher than normal and the subject may be experiencing perimenopause.
NEGATIVE: Two colored 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 indicates that the subject is probably not experiencing perimenopause in this cycle.
INVALID: Control line fails to appear. Insufficient specimen volume or incorrect test performance are the most likely reasons for an invalid result. Review the procedure and repeat with a new test. If the problem persists, discontinue using the test kit immediately and contact your local distributor.
Do not interpret the results in dim light.

【QUALITY CONTROL】

A procedural control is included in the test. A colored line appearing in the control line region (C) is considered an internal procedural control. It confirms sufficient specimen volume, adequate membrane wicking and correct procedural technique.
It is recommended that a positive FSH control (containing 25-250 mIU/mL FSH) and a negative FSH control (containing 0 mIU/mL FSH) be evaluated to verify proper test performance when a new shipment of tests is received.

【LIMITATIONS】

- Oral contraceptives 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. Do not make contraception decisions based on the results of this test. Please contact a doctor for your contraceptive needs.

【PERFORMANCE CHARACTERISTICS】

Accuracy

A multi-center clinical evaluation was conducted comparing results obtained using the FSH One Step Menopause Test Device,to another commercially available urine membrane FSH test. The study included 200 urine specimens (80 positive and 120 negative) and both assays identified 121 negative and 79 positive results. The results demonstrated >99% overall accuracy of the FSH One Step Menopause Test Device when compared to the other urine membrane FSH test.

FSH One Step Menopause Test Device vs. Other FSH Rapid Test

Method		Other FSH Rapid Test		Total Results
FSH One Step Menopause Test Device	Results	Positive	Negative	
	Positive	79	0	79
	Negative	0	121	121
Total Results		79	121	200

Relative Sensitivity:＞99.9% (95.3%~100%)* Relative Specificity:＞99.9% (96.9%~100%)*
Relative Accuracy: ＞99.9% (98.1%~100%)* 95% Confidence Intervals*

Sensitivity and Specificity

The FSH One Step Menopause Test Device can detect FSH at concentrations of 25 mIU/mL or greater. The addition of LH (200 mIU/mL), hCG (1000 mIU/mL) and TSH (200μIU/mL) to negative (0 mIU/mL FSH) and positive (25mIU/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
Atropine	20 mg/dL	Hemoglobin	10mg/dL
Bilirubin	2 mg/dL	Tetracycline	20 mg/dL
Ampicillin	20 mg/dL		

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

【BIBLIOGRAPHY】

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2. Perry S, O'Hanlan K. Natural Menopause: The Complete Guide. Reading, MA, Addison-Wesley, 1997.
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

	Consult instructions for use		Contains sufficient for <n> tests		Authorized representative in the European Community
	In vitro diagnostic medical device		Use-by date		Do not re-use
	Temperature limit		Batch code		Catalogue number
	Manufacturer		Date of Manufacture		Keep dry
	Keep away from sunlight		Do not use if package is damaged and consult		Meet the requirements of 98/79/EC Directive

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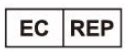

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