



FSH

One Step Menopause Test Device (Urine) Package Insert

A rapid, one step test for the qualitative detection of Follicle-stimulating hormone (FSH) in urine.

For professional in vitro diagnostic use only.

INTENDED USE

The FSH One Step Menopause Test Device (Urine) is a rapid chromatographic immunoassay for the qualitative detection of Follicle-stimulating hormone (FSH) level in urine to evaluate the onset of menopause in women.

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 (follicle stimulating hormone), 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 Device (Urine) 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 Device (Urine) 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 Device (Urine) is a rapid chromatographic 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 proper volume of specimen has been added and membrane wicking has occurred.

REAGENTS

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

PRECAUTIONS

- For professional *in vitro* diagnostic use only. Do not use after the expiration date.
- The test device should remain in the sealed pouch until use.
- All specimens should be considered potentially hazardous and handled in the same manner as an infectious agent.
- The test device should be discarded in a proper biohazard container after testing.

STORAGE AND STABILITY

Store as packaged in the sealed pouch at room

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

SPECIMEN COLLECTION AND PREPARATION

Urine Assay

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

- Test devices
- Disposable specimen droppers
- Package insert

Materials Required But Not Provided

- Specimen collection container
- Timer

WHEN TO TEST

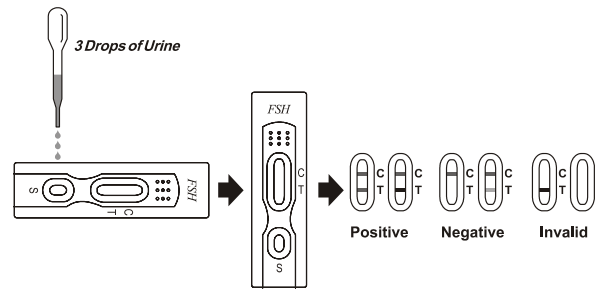
- If the subject is having monthly periods, perform the first test during the first week of the menstrual cycle (Days 2-7, with Day 1 being the first day of menstruation). Repeat with the second test 1 week later.
- If the subject is no longer having regular periods, perform the test at any time during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

DIRECTIONS FOR USE

Allow the test device, urine specimen and/or controls to equilibrate to room temperature

(15-30°C) prior to testing.

1. Bring the pouch to room temperature before opening it. Remove the test device from the sealed pouch and use it as soon as possible.
2. Place the test device on a clean and level surface. Hold the dropper vertically and **transfer 3 full drops of urine** (approx. 100 µL) to the specimen well (S) of the test device, and then start the timer. Avoid trapping air bubbles in the specimen well (S). See illustration below.
3. Wait for the red line(s) to appear. The result should be **read at 3 minutes**. Do not interpret the result after 10 minutes.



2. Oral contraceptives may affect the test and produce inaccurate results.
3. The test may not be used to determine fertility. It cannot be used to determine the subject's ability to become pregnant. Contraceptive decisions should not be made based on the results of this test. Please contact a doctor for contraceptive advice.

INTERPRETATION OF RESULTS

(Please refer to the illustration above)

POSITIVE: * **Two lines are visible and the test line (T) is the same as or darker than the control line (C).** A positive result indicates that FSH levels are higher than normal and the subject you may be experiencing perimenopause.

NEGATIVE: **Two lines are visible, but the test line (T) is lighter than the control line (C), or there is no test line.** A negative result indicates that the subject is probably not experiencing perimenopause in this cycle.

INVALID: Control line (C) 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.

QUALITY CONTROL

A procedural control is included in the test. A red line appearing in the control line region (C) is considered an internal procedural control. It confirms sufficient specimen volume 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 test devices is received.

LIMITATIONS

1. For professional in vitro diagnostic use.

Interfering Substances

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

Acetaminophen	20 mg/dL	Caffeine	20 mg/dL
Acetylsalicylic	20 mg/dL	Gentisic Acid	20 mg/dL
Ascorbic Acid	20 mg/dL	Glucose	2 g/dL
Acetoacetic Acid	2 g/dL	Hemoglobin	1 mg/dL
Bilirubin	2 mg/dL		

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

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.

PERFORMANCE CHARACTERISTICS

Accuracy

A multi-center clinical evaluation was conducted comparing results obtained using the FSH One Step Menopause Test Device (Urine) to another commercially available urine membrane FSH test. The study included 200 urine specimens: both assays identified 120 negative and 78 positive results. The results demonstrated 99% accuracy of the FSH One Step Menopause Test Device (Urine) when compared to the other urine membrane FSH test.

FSH Reference Method

Method		Other FSH Rapid		Total Results
Results		Positive	Negative	
FSH Test Device	Positive	78	2	80
	Negativ	0	120	120
	Total Results	78	122	200

Sensitivity: >99.9% (95.4%-100.0%)*

Specificity: 98.4% (94.2%-99.8%)*

Accuracy: 99.0% (96.4%-99.9%)*

* 95% Confidence Intervals

Sensitivity and Specificity

The FSH One Step Menopause Test Device (Urine) 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 □IU/mL) to negative (0 mIU/mL FSH) and positive (25 mIU/mL FSH) specimens showed no cross-reactivity.

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