

FSH

One Step

Menopause Test Device

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 Ovulation Test Device 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 One Step Menopause Test Device 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 One Step Menopause Test Device 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 which is darker than or the same shade as the line in the Reference Line Region. To serve as a procedural control, a colored line will always appear in the Reference Line Region, indicating that the 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 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

The kit can be stored 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

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

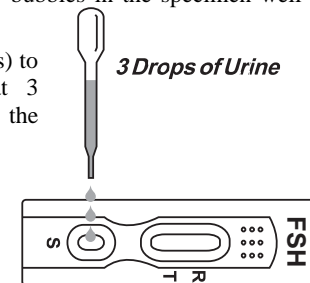
WHEN TO TEST

- If the subject is 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 device, urine specimen and/or controls to equilibrate to room temperature (15°-30°C) prior to testing.

1. 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. Start the timer. Avoid trapping air bubbles in the specimen well (S). See illustration below.
3. Wait for the colored line(s) to appear. Read results at 3 minutes. Do not read the result after 10 minutes.

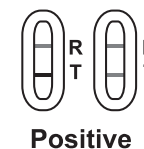


INTERPRETATION OF RESULTS

POSITIVE

Two lines are visible and the color intensity of the line in the Test Line Region (T) is the **same as or darker** than the line in the Reference Line Region (R).

A positive result means that the FSH level is higher than normal. Record the results and see the chart below to interpret results.





Negative

NEGATIVE

Two lines are visible, but the line in the Test Line Region (T) is **lighter** than the line in the Reference Line Region (R), or there is no visible 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

INVALID

If there is **no line in the Reference Line Region (R)** after 3-4 minutes, the result is invalid. The test should be repeated. The test is not reusable. The most likely reasons for an invalid result are that not enough urine specimen was used, or the test was performed the wrong way. Review the Directions for Use and repeat with a new test. If the problem persists, discontinue using the test kit and contact your distributor.

TEST INTERPRETATION

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

For patients experiencing perimenopausal symptoms plus irregular menstrual cycles:

1 st Test	2 nd 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.
Negative	Positive	
OR		
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:

1 st 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 Reference Line region (R) 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

1. The test works only when the test procedures are precisely followed.
2. Do not reuse the test device.
3. For professional *in vitro* diagnostic use only.
4. Oral contraceptive and pregnancy may affect the test and produce inaccurate results.
5. 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.
6. Keep out of the reach of children.

PERFORMANCE CHARACTERISTICS

Accuracy

A multi-center clinical evaluation was conducted comparing results obtained using the FSH One Step Menopause Test to another commercially available urine membrane FSH test. The results of the study, which included 200 urine specimens, demonstrated 99% accuracy of the FSH One Step Menopause Test when compared to the other urine membrane FSH test.

FSH One Step Test vs. Other FSH Rapid Test

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

Positive Agreement: 100.0% (95.4%-100.0%)*

Negative Agreement: 98.4% (94.2%-99.8%)*

Overall Agreement: 99.0% (96.4%-99.9%)*

*95% Confidence Interval

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 (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.

REFERENCE

1. Turkington CA. The Perimenopause Sourcebook. Contemporary Books, New York, NY. 1998.
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.

CLIA Category

Waived