FSH Rapid Test Dipstick (Urine)
Package Insert

REF FFS-101	English

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 Dipstick (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 Dipstick 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 Dipstick 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 immersing the test strip 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. 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.

【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 or label of the closed canister. The test must remain in the sealed pouch or closed canister until use. DO NOT FREEZE. Do not use beyond the expiration date.

NOTE: Once the canister has been opened, the remaining test(s) are stable for 90 days only.

【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 Dipstick — Package Insert

Materials required but not provided

Specimen collection containers — Timer

【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.

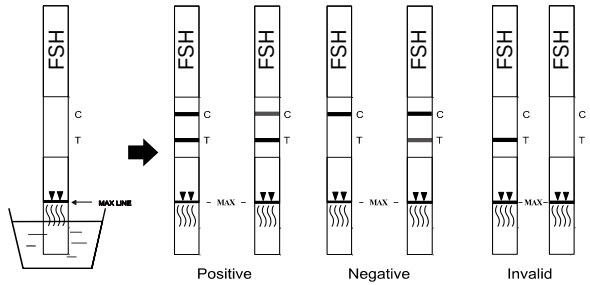
【DIRECTIONS FOR USE】

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

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 dipstick from the sealed pouch or closed canister and use it as soon as possible.

NOTE: For canister packaging, immediately close the canister tightly after removing the required number of the test dipstick(s). Record the initial opening date on the canister. Once the canister has been opened, the remaining test dipstick(s) are stable for 90 days only.

3. With arrows pointing toward the urine specimen, immerse the test dipstick vertically in the urine specimen for at least 10-15 seconds. Do not pass the maximum line (MAX) on the test dipstick when immersing the dipstick. See illustration below.
4. Place the test dipstick on a non-absorbent flat surface, start the timer and wait for the colored line(s) to appear. Read results 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	
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 Reference 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】

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 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	Negative	
FSH Rapid Test	Positive	85	0	85
	Negative	0	165	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 Dipstick 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】

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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

	Attention, see instructions for use		Tests per kit	EC REP	Authorized Representative
IVD	For in vitro diagnostic use only		Use by		Do not reuse
2°C 30°C	Store between 2-30°C	LOT	Lot Number	REF	Catalog #
	Do not use if package is damaged				

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Number: 145132102
Effective date: 2016-09-08