Rapid Response™

Follicle Stimulating Hormone (FSH) Menopause Test Cassette
(Urine)
REF FSH-1C25 Product 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 Rapid Response™ FSH Menopause Test Cassette 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 Rapid Response™ FSH Menopause Test Cassette 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 Rapid Response™ FSH Menopause Test Cassette 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 Control Line Region. 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 device contains anti-FSH antibodies conjugated to colored particles and anti-FSH antibodies 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.

Materials

Materials provided

- Test device
- Disposable specimen droppers
- Product insert

Materials required but not provided

- Specimen collection container
- Timer

Storage and Stability

- The kit can be stored at room temperature or refrigerated 35.6-86°F (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.

Collection and Storage of Specimens

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.

Specimens Storage

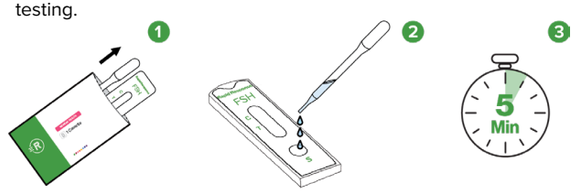
Urine specimens may be stored at 35.6-46.4°F (2°-8°C) for up to 48 hours prior to testing. For prolonged storage, specimens may be frozen and stored below -4°F (-20°C). Frozen specimens should be thawed and mixed before testing.

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.

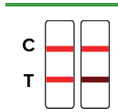
Test Procedure

Allow the test device, urine specimen and/or controls to equilibrate to room temperature (59-86°F; 15-30°C) prior to testing.

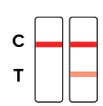


1. Remove the test device from the sealed pouch and use it as soon as possible.
2. Place the test device on a clean and level surface. Hold the dropper vertically and transfer 3 full drops of urine (approx. 120 µL) to the specimen well (S) of the test device. Start the timer. Avoid trapping air bubbles in the specimen well (S). See illustration below.
3. Wait for the colored line(s) to appear. Read results at 5 minutes. Do not read the result after 10 minutes.

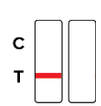
Results Interpretation



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 Control Line Region (C). A positive result means that the FSH level is higher than normal.



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 visible line in the Test Line Region (T). A negative result means that the FSH level is not elevated at this time.



INVALID: If there is no line in the Control Line Region (C) 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 Test Procedure 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:

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 Control 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 Rapid Response™ FSH Menopause Test Cassette to another commercially available urine membrane FSH test. The results of the study, which included 250 urine specimens, demonstrated 99.2 % accuracy of the Rapid Response™ FSH Menopause Test Cassette when compared to the other urine membrane FSH test.

Method		Other FSH Rapid Test		Total results
Rapid Response™ FSH Menopause Test Cassette	Results	Positive	Negative	
	Positive	98	2	100
	Negative	0	150	150
Total Results		98	152	250

Positive Agreement: >99.9%(96.2%-100.0%)*
Negative Agreement: 98.7% (95.3%-99.6%)*
Overall Agreement: 99.2% (97.1%-99.8%)*
*95% Confidence Interval

Sensitivity and Specificity

The Rapid Response™ FSH Menopause Test Cassette 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
Acetylsalicylic Acid	20 mg/dL
Ascorbic Acid	20 mg/dL
Acetoacetic Acid	2 g/dL
Bilirubin	1000 mg/dL
Caffeine	20 mg/dL
Gentisic Acid	20 mg/dL
Glucose	2 g/dL
Hemoglobin	500 mg/dL

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

Bibliography

1. 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.
2. Jacobs DS, Demott DR, Grady HJ, Horvat RT, Huestis DW, Kasten BL, Laboratory Test Handbook 4th Ed, Lippincott Williams and Wilkins, Baltimore, MD. 1996.
3. Speroff L, Glass RH, Kase NG, Clinical Gynecologic Endocrinology and Infertility 5th Ed, Williams and Wilkins, Baltimore, MD. 1994; 588.
4. Perry S, O'Hanlan K. Natural Menopause: The Complete Guide. Reading, MA, Addison-Wesley, 1997.
5. Turkington CA. The Perimenopause Sourcebook. Contemporary Books, New York, NY. 1998.

Glossary of Symbols

Consult instructions for use	Test per Kit	Authorized Representative
Store between 35.6°F to 86°F	Use by	Do Not Reuse
Lot Number	For *in vitro* diagnostic use only	Catalogue #

EC REP
MDSS GmbH
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