FSH Rapid Test Cassette (Urine)
Package Insert
For Self-testing

REF FFS-102H
English

A rapid test cassette for the qualitative detection of Follicle-Stimulating Hormone (FSH) in human urine sample. For self-testing in vitro diagnostic use only.

INTENDED USE

The FSH Rapid Test Cassette (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 AND PRINCIPLE

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 Follicle-Stimulating Hormone (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]

FSH Rapid Test Cassette is a rapid, one-step lateral flow immunoassay for the qualitative detection of FSH in urine to aid in the detection of menopause. The test utilizes a combination of antibodies including a monoclonal anti-FSH antibodies to selectively detect elevated levels of FSH.

REAGENT

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

PRECAUTIONS

Please read all the information in this package insert before performing the test.

- Do not use after the expiration date printed on the back of the foil pouch.
- The test should remain in the sealed pouch until use.
- Store in a dry place at 2-30 °C (36-86 °F). **Do not freeze**.
- Do not use if pouch is torn or damaged.
- Keep out of the reach of children.
- For *in vitro* diagnostic use only.
- Do not open the foil pouch until you are ready to start the test.
- Use the test only once. Do not dismantle and touch the test window of the test cassette.
- The used test should be discarded according to local regulation.

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. 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.

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 PROVIDED

- Test Cassettes
- Package Insert
- Droppers

MATERIALS REQUIRED BUT NOT PROVIDED

- Timer
- Specimen Containers

INSTRUCTIONS

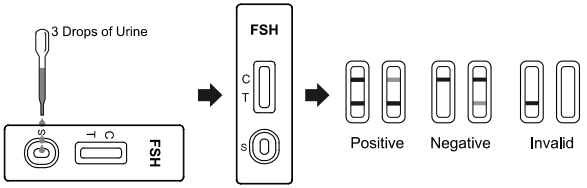
WHEN TO START TESTING

- If you are still having monthly periods, take the first test during the **first week of your cycle (days 2-7, with day 1 being the first day of menstruation)**. If the result is negative but symptoms persist, repeat with the second test one week later.
- If you are no longer having regular periods, take the test at any time during the month and repeat with the second test 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 cassette from the sealed pouch and use it immediately within one hour.
3. Place the test cassette on a clean and level surface. Hold the sample dropper vertically and transfer **3 drops of urine** to the specimen well (S) of the test cassette, avoid trapping air bubbles in the specimen well, and then start the timer. See illustration below.
4. Wait for the colored line(s) to appear. **Read the result at 3 minutes**. Do not interpret the result after 10 minutes.



READING THE RESULTS

(Please refer to the illustration)

POSITIVE: Two colored 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 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 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

For female experiencing premenopausal symptoms along with irregular menstrual cycles:

1st Test	2nd Test	Interpretation
Positive	Positive	Most likely in perimenopause. Discuss methods and therapies to promote good health after menopause with doctor. DO NOT immediately discontinue contraception.
Positive	Negative	May be in early stages of perimenopause. DO NOT immediately discontinue contraception.
OR		
Negative	Positive	

Negative	Negative	Most likely not experiencing perimenopause this cycle. If symptoms persist, repeat testing in the following month or review other possible causes for symptoms.

For female experiencing menopausal symptoms with NO menstrual cycle for the past 12 months:

1st Test	Interpretation
Positive	Menopause has most likely occurred. Test may be repeated. Discuss methods and therapies to promote good health after menopause with doctor.

CONTROL PROCEDURE

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.

LIMITATIONS

There is the possibility that this test may produce false positive or false negative results. Consult your physician before making any medical decisions. Invalid results are most likely caused by not following the instructions properly. Review the instructions and repeat the test with a new test. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

USEFUL INFORMATION

1. **Q: How does the test work?**
   A: As your body ages and produces less estrogen, FSH levels increase as the hormone tries to stimulate the ovaries to produce a healthy egg. This test measures FSH and can tell you whether your body is producing excess FSH as a result of low estrogen levels, signaling that your body is in the perimenopause stage.
2. **Q: When can I use the test?**
   A: We recommend performing the test using first morning urine as it contains the most hormone and will give the most accurate result. If you are still menstruating, we recommend testing during the first week of your cycle (see WHEN TO START TESTING) and then retesting one week later.
3. **Q: How will I know the test worked?**
   A: The appearance of a colored line in the Control line region (C) tells you that you followed the test procedure properly and the proper amount of urine was absorbed. If you do not see a line in the Control line region (C), you should review the procedure and repeat with a new cassette test. The test is not reusable. If you still experience problems, contact your distributor.
4. **Q: I received a positive result. Can I stop using contraception?**
   A: No, this test cannot determine fertility. Continue using contraception until your menopause status has been confirmed by your doctor.
5. **Q: How accurate is the test?**
   A: A clinical evaluation was conducted comparing the results obtained using FSH Rapid Test Cassette to another commercially available urine FSH test. The clinical trial included 250 urine specimens: both assays identified 85 positive and 165 negative results. The results demonstrated 100.0% overall accuracy of FSH Rapid Test Cassette when compared to the other urine FSH test.
6. **Q: How sensitive is the test?**
   A: FSH Rapid Test Cassette detects follicle-stimulating hormone (FSH) in urine at concentrations of 25 mIU/mL or higher. The addition of LH (1,000 mIU/mL), hCG (100 mIU/mL), and TSH (1,000 µIU/mL) to negative (0 mIU/mL FSH) and positive (25 mIU/mL FSH) specimens showed no cross-reactivity.
7. **Q: Do alcohol or common medications affect the test?**
   A: No, but you should consult your physician if you are taking any hormonal medication. Also, recent oral contraceptive use, breastfeeding, or pregnancy or any intake that can alter the hormonal balance can affect the test results.

BIBLIOGRAPHY

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4. Speroff L, Glass RH, Kase NG, Clinical Gynecologic Endocrinology and Infertility 5th Ed, Williams and Wilkins, Baltimore, MD. 1994; 588.
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IVD	For *in vitro* diagnostic use only
2°C 30°C	Store between 2-30°C
	Do not use if package is damaged
EC REP	Authorized representative in EU
REF	Catalog #
Σ	Tests per kit
	Use by
LOT	Lot number
	Manufacturer
2	Do not reuse
	Consult instructions for use
	Importer
	Distributor

Hangzhou Alltest Biotech Co., Ltd.
#550, Yinhai Street,
Hangzhou Economic & Technological Development Area
Hangzhou, 310018 P.R. China
Manufacturer
Web: www.alltests.com.cn Email: info@alltests.com.cn

CE 0123

EC REP
MedNet EC-REP GmbH Borkstrasse 10, 48163 Muenster, Germany

Czech Original Products s.r.o. - JOYMED.cz
Koulova 6, Praha 6, 160 00 - CZ
IČ: 08595771, DIČ: CZ08595771
+420 608 284 065 obchod@joymed.cz

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Koulova 6, Praha 6, 160 00 - CZ
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