PRODUCT CODE: 70178001

CE 0459

Atlas Home Menopause Midstream Test (Urine)

IVD **For in-vitro diagnostic and self-testing use**

Store at (2-30° C)

INTENDED USE

The Atlas Home Menopause Test is a test kit for the determination of Human Follicular Stimulating Hormone (FSH) concentration in urine specimens. Test results are read visually without the need for any instrument.

INTRODUCTION

The Atlas Home Menopause Test is a rapid, one-step test to detect FSH in urine to aid in the detection of menopause. Including a monoclonal FSH antibody to selectively. The test is conducted by urinating on the absorbent tip or immersing the tip in urine, and obtaining the result from the coloured lines.

PRINCIPLE

Women during fertility age experience regular menstruation cycles (bleeding) as a positive indication of their fertility and normal health conditions. The regularity of these menstruation cycles is maintained by the balance of four hormones, namely estrogen, Progesterone, Follicle Stimulating Hormone (FSH) and Luteinizing Hormone (LH). Menstruation cycles normally stop during pregnancy but also become less regular (a condition known as perimenopause) and finally stop (a condition known as menopause) with age when the body fails to maintain the balance in the levels of these hormones.

As women age, their bodies fail to retain FSH within its natural normal limits. A characteristic feature of perimenopause is a higher level of FSH than normal. The increase of FSH will occasionally suppress the levels of the other three hormones necessary to cause regular menstruation cycles. This in turn will sometimes lead to short or irregular cycles which signal the start of the perimenopause condition. Eventually, FSH continues to rise causing very low levels of the other three hormones ultimately preventing the menstrual cycle from occurring . This cessation of the menstrual cycle is known as menopause. Since FSH exists in higher levels than normal during perimenopause and menopause, detection of high FSH levels in urine is commonly used as a tool to determine perimenopause and menopause.

The low level of estrogen during perimenopause and menopause causes many discomforts such as hot flushes, sweating,sleeplessness, depression, palpitations (shivering), degeneration of breasts and genital organs, thinning and dryness of the vaginal epithelium (causing painful intercourse) and in the long run more serious conditions such as heart disease (coronary artery) and decrease in bone structure (osteoporosis) may develop. Many of these symptoms can be reduced by various treatments such as increased calcium intake and hormone replacement therapy. Therefore early detection of perimenopause and menopause can help women to plan and go through this natural process with minimal discomfort and health risks.

COMPONENTS

- Test Device
- Desiccant
- Package insert

PRECAUTIONS & WARNINGS

- Please read all the information in this leaflet before performing the test.
- If the package is not completely sealed do not use the test.
- The test should be performed in a well-lit area.
- Use the test device immediately after opening it.
- Do not touch the test window. This could affect results and may also be harmful.
- Do not use after the expiration date printed on the foil pouch.
- Do not freeze.
- Keep out of the reach of children.
- For *in vitro* diagnostic and self-testing use. Not to be taken internally.
- Do not open the test foil pouch until it has reached room temperature and you are ready to start the test.
- The pouch contains a silica gel pack to absorb humidity. Do not open the pack. Throw it away with the remainder of the test.
- At the end of the test, wrap everything you have used in a plastic bag and throw in the bin. Do not forget to wash your hands properly.

WHEN TO TEST

- 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). 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.

PROCEDURE

1. Read instructions carefully before use.
2. Determine the day you will begin testing (see the above section: “When to test”).
3. Check that the test is completely sealed and bring the pouch to room temperature before opening it.
4. Remove the midstream test from the foil pouch and familiarize yourself with the product.
5. Remove the cap and hold the midstream test by the handle with the exposed absorbent tip pointing downward directly into your urine stream for at least 10 seconds until it is thoroughly wet.
   Note: Do not urinate on the result window. If you prefer, you can urinate into a clean and dry container, then dip only the absorbent tip of the midstream test into the urine for at least 10 seconds.
6. After removing the midstream test from your urine, immediately replace the cap over the absorbent tip, lay the midstream test on a flat surface with the result window facing upward, and then begin timing.
7. As the test begins to work, you may notice a light red flow moving across the result window. Wait for the red line(s) to appear. **Read results in 1 - 5 minutes**. It is important that the background is clear before the result is read. Positive results may be observed in 1 to 5 minutes depending on the concentration of FSH.
   Note: Do not interpret the result after 10 minutes as false-positive results may occur.

HOW TO READ THE RESULTS

Positive:

Positive results= 2 lines with the (T) line the same or darker than the (C) line.

Two lines are visible with the test line (T) the same as or darker than the control line (C). This indicates that your FSH level is higher than normal and you may be experiencing perimenopause.

Negative:

Negative results = 2 lines with the (T) line lighter than the (C) line or one line in the (C) area.

Two lines are visible, but the test line (T) is lighter than the control line (C), OR the test line (T) does not appear. This indicates that you are probably not experiencing perimenopause in this cycle.

INVALID RESULT

Invalid results = no lines or 1 line in the (T) area.

The result is invalid if the control line (C) fails to develop, even if the test line (T) appears in the result window. The most likely reasons for control line failure are insufficient specimen volume or incorrect procedural techniques. Review the procedure and repeat the test with a new device. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

TEST INTERPRETATION

	1st Test	Interpretation
For women experiencing menopausal symptoms who have had **no menstrual cycle** for the past 12 months:	Positive	Menopause has most likely occurred. You may want to repeat the test, but discuss the results with your doctor to confirm them and discuss therapies to promote good health after menopause.

	1st Test	2nd Test	Interpretation
For women experiencing perimenopausal symptoms plus **irregular menstrual cycles**:	Positive	Positive	Most likely in perimenopause. Discuss results with your doctor. **Do not** discontinue contraception.
	Positive	Negative	May be in the early stages of perimenopause. Discuss results with your doctor. **Do not** discontinue contraception.
	OR		
	Negative	Positive	
	Negative	Negative	Most likely not experiencing perimenopause in this cycle. If symptoms persist, repeat testing in the following month or see your doctor about other possible causes for your symptoms.

PERFORMANCE CHARACTERISTICS

Sensitivity and Accuracy:

All specimens with FSH concentration equal to or higher than 25 mIU/mL are accepted as positive results and all specimens less than 25 mIU/mL or in basal level are considered negative results. Therefore, the sensitivity concentration of Atlas Menopause Test Device (Urine) is determined to be 20 mIU/mL and the accuracy is 98%.

Interfering substances:

None of the substances mentioned below at the concentration tested interfered with the expected test results of the Atlas Home Menopause Test Cassette.

Analyte	Concentration	Analyte	Concentration
Acetaminophen	20 mg/dL	Salicylic Acid	20 mg/dL
Acetoacetic acid	2000mg/dL	Phenothiazine	20 mg/dL
Ascorbic Acid	20 mg/dL	EDTA	20 mg/dL
B-hydroxybutyrate	2000mg/dL	Acetylsalicylic Acid	20 mg/dL
Caffeine	20 mg/dL	Benzoylecgonine	10 mg/dL
Ephedrine	20 mg/dL	Cannabinol	10 mg/dL
Gentisic Acid	20 mg/dL	Codeine	10 mg/dL
Phenylpropanolamine	20 mg/dL	Methadone	10 mg/dL
Methanol	1.0 %	Ethanol	1.0 %

QUESTIONS AND ANSWERS

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.

Q: When can I use the test?

A: We recommend performing the test using first morning urine as it contains the most hormones 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 TEST) and then retesting one week later.

Q: I received a positive result. Can I stop using contraception?

A: No, this test cannot determine fertility. Continue using contraception until your test results have been confirmed by your doctor.

Q: I am not sure that I held the test in my urine stream long enough. Will I still get an accurate result?

A: In order to receive an accurate result, you should hold the absorbent tip of the test in your urine stream for at least 10 seconds and wait 1-5 minutes to read the result. If the line in the reference window (C) fails to develop, you should repeat with a new test.

Q: How accurate is the test?

A: In laboratory studies, the test was shown to be more than 98% accurate overall.

Q: How will I know the test worked?

A: The appearance of a red line in the reference window (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 reference window (C), you should review the procedure and repeat with a new test. The test is not reusable. If you still experience problems, contact your distributor.

Q: Will the amount of liquid I drink affect the result?

A: Heavy intake of fluids before testing will dilute the hormone level in your urine. Limitation of the amount of liquid intake for about two hours before you collect your urine is suggested.

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	Product Reference No.		For in-vitro diagnostic use.
	Caution.		Store at
	Read product insert before use.		Number of tests in the pack.
	Lot (batch) number.		Manufacturer.
	Expiry date.		Manufacturer telephone number.
	Manufacturer fax number.		Manufacturing Date