

# FSH

## One Step Home Menopause Test Midstream (Urine) Package Insert

### INSTRUCTIONS

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
- Store in a dry place at 2°-30°C (36°-86°F)
- Do not freeze
- Keep out of the reach of children
- For *in vitro* diagnostic use only. Not to be taken internally
- Do not open the foil pouch until you are ready to start the test



### 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 FSH (Follicle Stimulating Hormone), which normally regulates the development of a female's eggs. 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.

The FSH One Step Home Menopause Test Midstream (Urine) is a rapid, one-step chromatographic 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 FSH antibody to selectively detect elevated levels of FSH. The assay is conducted by urinating on the absorbent tip or immersing the tip in urine, and obtaining the result from the colored lines.

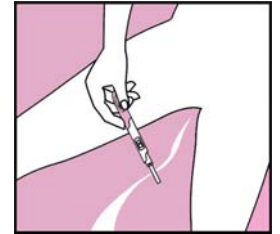
### HOW TO USE

#### WHEN TO TEST

- If you are still having monthly periods, take the 1st test during the first week of your cycle (days 2-7, with day 1 being the first day of menstruation). Repeat with the 2nd 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

1. Remove the midstream test from the foil pouch and familiarize yourself with the product.
2. Remove the Cap and place it over the Thumb Grip. See the large illustration at the top of this insert.
3. Hold the midstream test by the capped Thumb Grip with the exposed Absorbent Tip pointing downward directly into your urine stream for at least 10 seconds. **Do not urinate on the Test and Reference Windows.** (If you prefer, you can urinate into a clean dry container. Dip only the Absorbent Tip of the Test into the urine for at least 10 seconds).
4. 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 Test and Reference windows facing upwards, and then begin timing.
5. As the test begins to work, you may notice a light pink color flowing through the Test and Reference Windows. **Read results at 5 minutes.** If no colored line appears, wait one minute longer. Do not read the result after 10 minutes.



### HOW TO READ THE RESULTS

<p><b>POSITIVE</b> Two lines are visible and the line in the test window (T) is the same as or darker than the one in the reference window (R). This indicates that your FSH level is higher than normal and you may be experiencing perimenopause. See chart below.</p>	<p><b>NEGATIVE</b> Two lines are visible, but the line in the test window (T) is lighter than the one in the reference window (R), OR there is no line in the test window (T). This indicates that you are probably not experiencing perimenopause in this cycle.</p>	<p><b>INVALID</b> Reference line fails to appear. The result is invalid if no red line appears in the reference window (R), even if a line appears in the test window (T). You should repeat with a new midstream test.</p>
--	---	---

### TEST INTERPRETATION

For women experiencing menopausal symptoms who have had **no menstrual cycle** for the past 12 months:

For women experiencing perimenopausal symptoms plus **irregular menstrual cycles**:

1 <sup>st</sup> Test	Interpretation
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.

1 <sup>st</sup> Test	2 <sup>nd</sup> Test	Interpretation
Positive	Positive	Most likely in perimenopause. Discuss results with doctor. <b>Do not</b> discontinue contraception.
Positive	Negative	May be in early stages of perimenopause. Discuss results with doctor. <b>Do not</b> discontinue contraception.
Negative	Positive	
Negative	Negative	Most likely not experiencing perimenopause this cycle. If symptoms persist, repeat testing in the following month or see your doctor about other possible causes for your symptoms.

### QUESTIONS AND ANSWERS

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 TEST) and then retesting one week later.
3. 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.
4. 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 3 minutes to read the result. If the line in the reference window (R) fails to develop, you should repeat with a new test.
5. Q: How accurate is the test?  
A: In laboratory studies, the test was shown to be more than 98% accurate overall.
6. Q: How will I know the test worked?  
A: The appearance of a red line in the reference window (R) 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 (R), you should review the procedure and repeat with a new test. The test is not reusable. If you still experience problems, contact your distributor.

