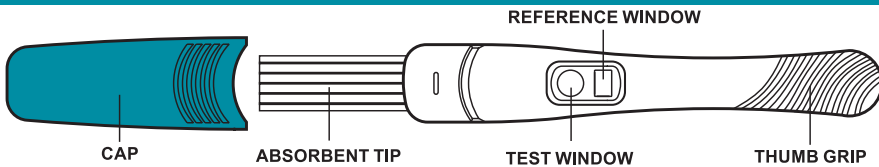


# FSH Menopause Predictor Test

## STORAGE AND HANDLING:

- Please read all the information in this leaflet before performing the test.
- Do not use after the expiration date stamped on the foil pouch.
- Store in a dry place at room temperature 15°-30°C (59°-86°F). Do not freeze.
- For in-vitro diagnostic use only. Not to be taken internally. Keep out of reach of children.
- Do not open the foil pouch until you are ready to start the test.



## TEST INFORMATION

The **FSH Menopause Predictor Test** is a rapid test for the detection of FSH (Follicle Stimulating Hormone) in urine to help predict menopause. Menopause is the permanent ending of menstruation. It is usually not diagnosed until one full year after a woman's last menstrual period. The time leading up to menopause, and the 12 months after, is known as perimenopause. Many women experience symptoms during this time. These symptoms can include hot flashes, irregular menstrual cycles, sleep disorders and vaginal dryness. Hair loss, anxiety and mood swings, short-term memory loss and fatigue are some other possible symptoms.

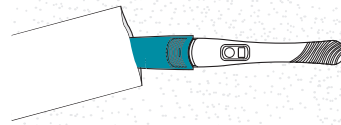
Perimenopause starts when hormone levels in the female body change. As the body ages, it produces less and less estrogen. FSH levels then increase as the hormone tries to stimulate the ovaries to produce a healthy egg. Therefore, testing for FSH can help determine if a woman's body is producing too much FSH because of low estrogen levels and is in the perimenopause stage. If a woman knows she is in this stage, she can take steps to keep her body healthy and avoid the health risks that can come with menopause. These health risks include osteoporosis, increased blood pressure and cholesterol, and increased risk of heart disease.

## WHEN TO TEST

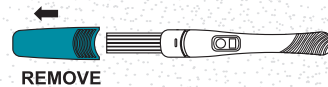
- If you still have monthly periods, take the first test during the first week of your cycle (Days 2-7, with Day 1 being the first day of menstruation). Repeat with the second test 1 week later.
- If you no longer have regular periods, take the test at any time during the month. Repeat with the second test 1 week later.

## HOW TO USE

- Remove the Test from the foil pouch.

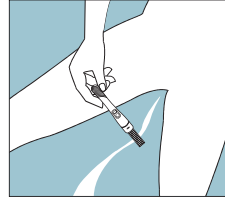


- Remove the Cap to expose the Absorbent Tip.

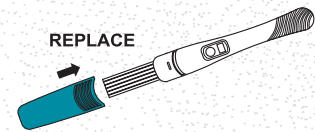


- Hold the Test Wand by the Thumb Grip with the exposed Absorbent Tip downward and place directly into the urine stream for at least 10 seconds (see

image). 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 Wand into the urine for at least 10 seconds.)



- While holding the Absorbent Tip downward, immediately replace the cap and lay the Test Wand on a flat surface with the Test and Reference Windows facing upward while you wait for the test result. **DO NOT** move the test while the results are developing.



As the test begins to work, you may notice a light pink color or horizontal lines flowing through the Test and Reference Windows. Wait 3 minutes from the time you held the Absorbent Tip in the urine to read the results. If no result appears, wait one minute longer. **Do not read the result after 8 minutes have passed.**

## HOW TO READ THE RESULTS

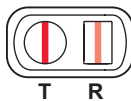
### POSITIVE

Two lines are visible and the color intensity of the Test Line (T) is the **same** as the Reference Line (R).



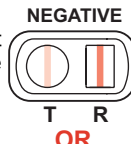
OR

Two lines are visible and the color intensity of the Test Line (T) is **darker** than the Reference Line (R).



### NEGATIVE

Two lines are visible, but the Test Line (T) is **lighter** than the Reference Line (R).



OR

There is a Reference Line (R), but there is **NO** visible Test Line (T).



### INVALID

If you see **no Reference Line (R)** after 3-4 minutes, the result is invalid. You should repeat the test. The test is not reusable. The most likely reasons for an invalid result are that not enough urine sample was used, or the test was performed the wrong way. Review the "HOW TO USE" section and repeat with a new test.



A positive result means that your FSH level is higher than normal. Record your results in the table to the right. See the chart below to interpret your results.

A negative result means that your FSH levels are not elevated at this time. Record your results in the table to the right. See the chart below to interpret your results.

TABLE I: YOUR TESTING RESULTS

	1st Test		2nd Test	
Circle Your Results	POS.	NEG.	POS.	NEG.

## CHART I: TEST INTERPRETATION

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

1st Test	2nd Test	Interpretation
Positive	Positive	Most likely in perimenopause. Discuss results with doctor. DO NOT discontinue contraception.
Positive	Negative	May be in early stages of perimenopause. Discuss results with doctor. DO NOT discontinue contraception.
Negative	Positive	
Negative	Negative	Most likely not experiencing perimenopause during this cycle. If symptoms persist, repeat testing the next month or see your doctor about other possible causes of your symptoms. DO NOT discontinue contraception.

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

1st Test	Interpretation
Positive	Menopause has most likely occurred. You may want to repeat the test, but see your doctor to confirm results and discuss therapies to promote good health after menopause.

## QUESTIONS AND ANSWERS

### 1. How does the menopause predictor test work?

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 too much FSH because of low estrogen levels. This can signal that you are in the perimenopause stage.

### 2. When can I use the test?

We recommend performing the test using first morning urine as it contains the most hormone. This 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 1 week later.

### 3. If I see pink shading or horizontal lines in the result windows, is this normal?

After urine is added, you will see a pink color gradually move across the Test and Reference windows. You may also see horizontal streaks. This is completely normal and indicates that the test is working properly.

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

In order to get 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 fails to develop, you should repeat the test.

### 5. Can I make contraceptive decisions based on the results of this test?

No. This test cannot determine fertility. Continue to use contraception until your test results have been confirmed by your doctor.

### 6. How accurate is the test?

In laboratory clinical studies, the test was shown to be >99% accurate when compared with another over-the-counter menopause test. In consumer studies, the test was shown to be >94% accurate overall.

### 7. How will I know the test worked?

You must see a line in the Reference Window. If after 3-4 minutes you do not see a line in the Reference Window, then the test did not work properly. (Please refer to INVALID RESULT.) You should review the instructions and repeat with a new test.

### 8. Do alcohol or common medications affect the test?

No, alcohol or common medications should not affect the test results, but you should consult your physician if you are taking any hormonal medication. Oral contraceptive use and pregnancy could also affect the test results.