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. 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 Menopause Test Device is a rapid test that qualitatively detects the FSH level in urine specimen at the onset of menopause.

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 Reference Line Region. To serve as a procedural control, a colored line will always appear in the Reference Line Region, indicating that the proper volume of specimen has been added and membrane wicking has occurred.

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°C-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.
NEGATIVE

Two lines are visible, but the line in the Test Line Region (T) is lighter than the line in the Reference Line Region (R), 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. Record the results and see the chart below to interpret results.

INVALID

If there is no line in the Reference Line Region (R) 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 Directions for Use 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:

<table>
<thead>
<tr>
<th>1st Test</th>
<th>2nd Test</th>
<th>Interpretation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Positive</td>
<td>Positive</td>
<td>Most likely in perimenopause. Discuss with patient methods and therapies to promote good health after menopause. Patient should NOT immediately discontinue contraception.</td>
</tr>
<tr>
<td>Positive</td>
<td>Negative</td>
<td>May be in early stages of perimenopause. Patient should NOT immediately discontinue contraception.</td>
</tr>
<tr>
<td>OR</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Negative</td>
<td>Positive</td>
<td>Most likely not experiencing perimenopause this cycle. If symptoms persist, repeat patient testing in the following month or review other possible causes for symptoms.</td>
</tr>
<tr>
<td>Negative</td>
<td>Negative</td>
<td></td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Interpretation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Positive</td>
</tr>
</tbody>
</table>

QUALITY CONTROL

A procedural control is included in the test. A colored line appearing in the Reference Line region (R) is an internal procedural control. It confirms sufficient specimen volume, adequate membrane wicking and correct procedural technique.

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.

PERFORMANCE CHARACTERISTICS

Accuracy

A multi-center clinical evaluation was conducted comparing results obtained using the FSH One Step Menopause Test to another commercially available urine membrane FSH test. The results of the study, which included 200 urine specimens, demonstrated 99% accuracy of the FSH One Step Menopause Test when compared to the other urine membrane FSH test.

FSH One Step Test vs. Other FSH Rapid Test

<table>
<thead>
<tr>
<th>Method</th>
<th>Other FSH Rapid Test</th>
<th>Total Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>FSH One Step Test</td>
<td>Results</td>
<td></td>
</tr>
<tr>
<td>Positive</td>
<td>78</td>
<td>2</td>
</tr>
<tr>
<td>Negative</td>
<td>0</td>
<td>120</td>
</tr>
<tr>
<td>Total Results</td>
<td>78</td>
<td>122</td>
</tr>
</tbody>
</table>

Positive Agreement: 100.0% (95.4%–100.0%)*
Negative Agreement: 98.4% (94.2%–99.8%)*
Overall Agreement: 99.0% (96.4%–99.9%)*
*95% Confidence Interval

Reproducibility and Precision

To demonstrate the reproducibility and precision of the FSH One Step Menopause Test when used by lay persons, 35 non-lab participants performed the test on blinded and coded panels of 5 FSH-spiked urine samples at 0 (negative), 12.5 (50% cutoff), 25 (cutoff), 37.5 (+50% cutoff), and 75 mIU/mL (strong positive) concentrations. Study participants were asked to read the package insert, perform the test and record test results. Study data showed a >99% agreement with expected results, including those samples that were at ±50% of the cutoff concentration, demonstrating the reproducibility and precision of the test.

Sensitivity and Specificity

The FSH One Step Menopause Test Device 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
- Acetaminophen 20 mg/dL
- Acetylsalicylic Acid 20 mg/dL
- Acetaminophen 20 mg/dL
- Acetylsalicylic Acid 20 mg/dL
- Acetaminophen 20 mg/dL
- Acetylsalicylic Acid 20 mg/dL

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

REFERENCE


CLIA Category - Waived

BTNX Inc.
570 Hood Road, Unit 23
Markham, ON L3R 4G7 Canada
(905) 944 9565

Rev 03-12042007
It tests urine for the presence of FSH, or follicle-stimulating hormone. Fine, but here’s the first potential trap: Levels of FSH in the blood correlate poorly with menopausal symptoms. So, if a blood test that looks for FSH isn't a reliable marker, neither is the urine test. As disappointing and surprising as it may seem, many aspects of the menopause process remain a mystery to medical science. The medical definition of menopause is when menstrual periods stop for 12 months as a consequence of the ovaries shutting down. Menopause is not defined by a blood test, or a urine test, or WONDFO 2PCS One Step FSH(follicle-stimulating hormone) Menopause Urine Test 2T. Quick and easy operation and 99% accuracy. Earliest detection, greatest sensitivity level - 25 mIU/mL. Wondfo® One Step FSH Urine Test detects this particular hormone level in urine. 2. What should I do if I’m unsure about the test result? If it is hard to compare the color intensity between the test line and the control line, repeat the test in 5 to 7 days after the first test. 3. What does it mean if the test is positive? Positive results show that the FSH level in your body is at or above 25 mIU/mL. One pouch containing a test device and a desiccant. The desiccant is for storage purpose only, and is not used in the test procedures. Insert with instructions for use. FSH (Follicle stimulating hormone) - During menopause FSH will INCREASE. An FSH of 40 IU/L or higher is a strong marker for menopause (9). Leutinizing hormone (LH) - Like FSH, LH will also increase during menopause. The next most important step is what you decide to do as a result of that information. As a woman, you will find that menopause hits certain women harder than others. Testing for menopause is relatively easy and can help you to confirm that you are in menopause. The symptoms of menopause can be vague and differ from person to person, so using a tool such as lab tests can be effective in helping you understand what is happening in your body. These tests are covered by insurance and relatively easy to interpret and understand. The Menopause-FSH Test checks the level of FSH hormone (Follicle-Stimulating Hormone) in urine in order to verify a possible high value. This change generally begins around 45 years of age, but the real signs appear towards the age of 55. The irregularity of menstrual cycle can be a first indicator of the beginning of menopause. What are menopause and FSH? Menopause is a physiological event which corresponds to the end of the female fertile age.