INTENDED USE
The OvuPac OneStep LH Ovulation Test is an immunochromatographic one-step in vitro assay. It will qualitatively or semi-quantitatively detect the presence of human luteinizing hormone in urine and is designed to be used to predict the time of ovulation in women. It is a fast, accurate, and convenient method to determine when the female body will ovulate, the most likely time for conception to occur.

SUMMARY AND EXPLANATION OF THE TEST
Ovulation is the release of an egg from the ovary. The few days around ovulation are the most likely times for conception to occur. The OvuPac OneStep LH Ovulation Test is specifically designed to detect the LH surge.

The OvuPac OneStep LH Ovulation Test

The OvuPac OneStep LH Ovulation Test utilizes an immunochromatographic strip with an LH antibody pad coated with goat anti-LH antibody and goat anti-rabbit IgG antibody with a colored anti-LH antibody pad. A reaction pack containing an antibody-antigen-dye-conjugate-sandwich in the test zone visible as a pink-rose band. Anti-LH-antibody-dye-complex reacts with free LH in the urine specimen forming an antibody-antigen-dye-conjugate-sandwich in the test zone visible as a pink-rose band, the intensity of which reflects the amount of LH in the sample specimen. Finally, an immobilized reagent in the control zone "C" captures a dye conjugate forming a pink-rose control band, which is calibrated to correspond to a 30 mIU LH/ml intensity relative to the test band. At five minutes the test is complete and the control band intensity and test band intensity are visually compared to determine the concentration of LH present in the urine sample.

A test band of equivalent or greater intensity than the control band is a positive result, which indicates LH is present in the test sample at or above 30 mIU/ml, and suggests that the LH surge is occurring. A test band of lesser intensity than the control band is a negative result, and indicates the LH concentration of the specimen is below 30 mIU/ml, a good indicator that the LH surge is not occurring.

MATERIALS PROVIDED

1. Test Device, 5 / 10 pcs.
2. Dropper, 5 / 10 pcs.
3. Urine Cup, 5 / 10 pcs.
4. Instructions.

STORAGE AND STABILITY
Store the test kit below 28°C; do not freeze. Refer to the expiration dates of the individual components for stability information.

WARNINGS AND PRECAUTIONS
1. The test kit is for in vitro diagnostic use only.
2. Do not use beyond the expiration date.

SAMPLE COLLECTION AND PREPARATION

COLLECTION TIME
Collect urine once per day, at about the same time between 10:00 A.M. and 8:00 P.M. Do not use first morning urine as a sample.

COLLECTION PROCEDURE
Collect the urine sample using the Urine Cup included with this kit, or in a clean, dry container, either plastic or glass.

The test device should be kept at room temperature (15°C-28°C) until use. After use, refrigerated samples reach room temperature before starting the test (this will take about 30 minutes). For best results, test the urine on the same day it is collected.

Test Procedure

STEP 1: WHEN TO START TESTING
Determine the length of the menstrual cycle
The length of the menstrual cycle is the number of days from the first day of menstrual bleeding to the day before bleeding begins on the next period.

Determine the usual length of the menstrual cycle over the last few months. Then, refer to the Cycle Chart to determine on which day of the menstrual cycle to begin testing. If your cycle is less than twenty-one days or greater than forty days, consult a physician.

<table>
<thead>
<tr>
<th>Cycle Length</th>
<th>Day of Cycle to Begin Testing</th>
</tr>
</thead>
<tbody>
<tr>
<td>21 days</td>
<td>day 9</td>
</tr>
<tr>
<td>22 days</td>
<td>day 6</td>
</tr>
<tr>
<td>23 days</td>
<td>day 7</td>
</tr>
<tr>
<td>24 days</td>
<td>day 8</td>
</tr>
<tr>
<td>25 days</td>
<td>day 9</td>
</tr>
<tr>
<td>26 days</td>
<td>day 10</td>
</tr>
<tr>
<td>27 days</td>
<td>day 11</td>
</tr>
<tr>
<td>28 days</td>
<td>day 12</td>
</tr>
<tr>
<td>29 days</td>
<td>day 13</td>
</tr>
<tr>
<td>30 days</td>
<td>day 14</td>
</tr>
<tr>
<td>31 days</td>
<td>day 15</td>
</tr>
<tr>
<td>32 days</td>
<td>day 16</td>
</tr>
<tr>
<td>33 days</td>
<td>day 17</td>
</tr>
<tr>
<td>34 days</td>
<td>day 18</td>
</tr>
<tr>
<td>35 days</td>
<td>day 19</td>
</tr>
<tr>
<td>36 days</td>
<td>day 20</td>
</tr>
<tr>
<td>37 days</td>
<td>day 21</td>
</tr>
<tr>
<td>38 days</td>
<td>day 22</td>
</tr>
<tr>
<td>39 days</td>
<td>day 23</td>
</tr>
<tr>
<td>40 days</td>
<td>day 24</td>
</tr>
</tbody>
</table>

Example: If your cycle is normally twenty-six days, the Cycle Chart indicates testing should begin on day 10. The following calendar shows how to determine day 10.

<table>
<thead>
<tr>
<th>Sample Calendar</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
</tr>
<tr>
<td>8</td>
</tr>
<tr>
<td>15</td>
</tr>
<tr>
<td>22</td>
</tr>
</tbody>
</table>

Φ = The first day of menstrual bleeding.
ν = The day to begin testing (Day 10).

STEP 2: TESTING PROCEDURE
1. Collect a urine sample in the Urine Cup according to the collection instructions. Allow an unopened foil test pouch and the urine sample to come to room temperature.
2. Open the foil pouch by tearing along the notch and remove the Test Device and dropper.
3. Holding the dropper vertically, transfer four drops of urine to the sample well "S" of the test device.
4. Read the results at five minutes.

IMPORTANT: Do not read the results after more than five minutes. To avoid confusion, discard the device after reading the results.
INTERPRETATION OF RESULTS

Within three to five minutes, two color bands will appear. A positive result may be seen as early as three minutes, however to confirm a negative result, wait the entire five minute period.

To determine your result, compare the color intensity, i.e. shade of color, lightness or darkness of color, of the test band “T” to the control band “C.” In determining a positive or negative result, it is important to compare the color intensity for this will indicate whether or not the LH surge is in progress.

1. Positive for the LH Surge
   If the test band is of equal or greater intensity (equal or darker) than the control band, this is a positive result and a good indication that the LH surge is occurring.

2. Negative for the LH Surge
   If the test band is of lesser intensity (lighter) than the control band or cannot be seen, this means the LH level of the sample is at or near its basal (normal) level and that the LH surge is not in progress.

3. Invalid Result
   If no control band appears within five minutes, the test result is invalid and should be ignored. A visible control band is needed in all cases to confirm proper test operation. No control band indicates either the test procedures were not followed correctly, or the test reagents failed. Carefully review the test procedures and retest with a fresh (unused) device.

HOW TO RECOGNIZE THE LH SURGE

After each test, you must decide if you are having an LH surge. If your test result is positive, you are probably having an LH surge. An LH surge can last from one to three days. Ovulation is most likely to occur sometime in the day and a half following the first day of the LH surge.

If your test result is negative, you are probably not having an LH surge. Remember that a rose-pink test band lighter than the control band shows that there is only a very low level of LH in your urine.

WHEN TO STOP TESTING

Unless otherwise specified by a doctor, stop testing once the LH surge is detected. Leftover unused tests may be saved for use later, but as six to ten days of testing may be needed to detect the LH surge, additional tests may be required.

NOTE: Listed below are some of the reasons why a surge may not be detected.

1. Urine is collected at the wrong time of day, such as first morning urine which should not be used.
2. The concentration of LH is too low to accurately detect.
3. Testing is performed too early or too late in the menstrual cycle.
4. Testing is stopped before the surge occurs, and should have been continued for a few more days. A 10-Day test kit is also available for this reason.
5. A LH surge did not occur during this menstrual cycle.

THE LH SURGE, OVULATION & PREGNANCY

A pregnancy begins with conception. A child is conceived when the male sperm successfully fertilizes the female egg. Successful fertilization is most likely during a twenty-four hour period one to three days following the LH surge. Since this ovulation “window” only opens once per month, and for only about twenty-four hours, being able to predict it is very helpful when trying to become pregnant.

Therefore, you should have intercourse during the one to three days following the LH surge to have the best chance of becoming pregnant.

LIMITATIONS OF THE TEST

1. Directions must be followed carefully for accurate results.
2. Do not open the foil pouch until ready to conduct the test.
3. Do not use the results of this test as an aid for contraception.
4. Consult a doctor if irregular or unusually long cycles are experienced.
5. Urine from pregnant women, women in menopause, or after receiving a hCG shot (injection) should not be used with this test, and will cause inaccurate results.
6. Do not use the test kit after the expiration date listed on the box.
7. The parts of this kit are a matched set and should always be used together.
8. A test device can only be used once. Discard the test after use.
9. Do not compare color bands from different devices.

QUESTIONS & ANSWERS

1. Should I restrict my diet before taking the test? No, diet will not affect the test results.
2. Does alcohol, aspirin, or any other common drug affect the test? No, but some hormonal medications can interfere with test results. If such medications are being taken or are suspected, seek professional advice from a physician to confirm the test results.
3. Should the test be used for contraception? No, the test is not designed to prevent or help prevent conception and should not be used to do so.
4. Why is first morning urine not a good sample? If first morning urine is used with the test, the first day of the LH surge may not be detected. The best time to collect the urine is between 10:00 A.M. and 8:00 P.M. Always try to collect it at about the same time each day.
5. Today's control band is a different shade of rose-pink than yesterday's control band. Is this a concern? Variations in the color of the control band will not affect the test result. Always compare the color of the test band to that of the control band of the same device on the day the test is performed.
6. Can test results be interpreted after five minutes? No. Test results must be interpreted within 3-5 minutes. Though a positive result should not change for several days, a negative result may change to a false positive within minutes after the end of the testing period, which would not be an accurate reading. It is always best to read the results at the 5 minutes testing period and then discard the test to avoid confusion.
7. A pink background color and vertical streaking appeared in the result area during the testing period. Is this a concern? Each urine sample will vary in its chemical makeup, as will the humidity of the air in testing chamber (room). Such variations in physical conditions can cause the vertical streaking and/or the pink background color but will not affect the test results. As long as the control band appears within five minutes, the test is working properly.

BIBLIOGRAPHY