**Intended Use**
The *bodytalk®* Ovulation Test is an immunochromatographic one-step in vitro assay. It will detect the presence of human luteinising hormone (LH) 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. This device is intended for in home testing.

**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 time for conception to occur. The *bodytalk®* Ovulation Test is specifically designed to detect the LH surge.

Luteinising hormone (LH) in elevated quantities causes ovulation. During the menstrual cycle only a small amount of LH is made, but in the middle of the cycle LH briefly increases. This increase is called the “LH surge” and precedes ovulation. Conception is most likely to occur within thirty-six hours following the LH surge. “The presence of an LH surge means that it is likely that ovulation will occur. However, the LH surge is no guarantee that ovulation does occur; it is only presumptive evidence that it might.”

A test band of equivalent or greater colour intensity than the control band is a positive result, which indicates LH is present in the test sample, and suggests that the LH surge is occurring. A test band of lesser colour intensity than the control band is considered a negative result, and indicates that the LH surge is not occurring. The presence of the control band also acts as a procedural control. Its presence indicates that the device is functioning correctly and that the reagents are still immunochemically active.

**Reagents and Materials Provided**
1. 10 individual foil wrapped Reaction Dipstick Tests.
2. 1 Re-usable urine collection cup with Dipstick Stand.
3. Usage Instructions.

**Storage and Stability**
Store the test kit below 28ºC; 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.

**Specimen Collection and Preparation**

**Collection Time**
Collect urine once per day, at about the same time each day, between 10:00 AM and 8:00 PM.

**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 sample may be stored at room temperature (15º-28ºC) for up to eight hours, or in the refrigerator for up to twenty-four hours. Do not freeze the urine sample.

Let 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**
The length of the menstrual cycle is the number of days from the first day of menstrual bleeding to the day before bleeding begins 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 medical practitioner.

**Cycle Chart**

<table>
<thead>
<tr>
<th>Cycle Length</th>
<th>Day of Cycle to Begin Testing</th>
<th>Cycle Length</th>
<th>Day of Cycle to Begin Testing</th>
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<tbody>
<tr>
<td>21 Days</td>
<td>Day 5</td>
<td>31 Days</td>
<td>Day 15</td>
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<tr>
<td>30 Days</td>
<td>Day 14</td>
<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 calendar below shows how to determine day 10.

**Sample Calendar**

1 2 3 4 5 6 7
8 9 10 11 12 13 14
15 16 17 18 19 20 21
22 23 24 25 26 27 28

1 - The first day of menstrual bleeding
10 - 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 Dipstick.
3. Carefully place the Test Dipstick vertically into the urine cup, test dipstick holder, as shown.

**IMPORTANT:** Do not allow the urine level to exceed the line indicated by the arrows near the bottom of the test dipstick; otherwise the test will not perform correctly.
4. Read the results at 5 minutes.

**IMPORTANT:** Do not read the results after more than five minutes. To avoid confusion, discard the device after reading the results.
Step 3: 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 colour, lightness or darkness of colour, of the control band to the central band. In determining a positive or negative result, it is important to compare the control 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 Recognise 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 pink-rose 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 different times of each day.
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.
5. A LH surge did not occur during this menstrual cycle.

**Optimise your chance for a baby**

A pregnancy begins with conception. A child is conceived when the male sperm successfully fertilises the female egg. Successful fertilisation is most likely during the one to three day “window” following the LH surge. Since this ovulation “window” only opens once per cycle, being able to identify this “window” 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. For in vitro diagnostic use only.
2. Directions must be followed carefully for accurate results.
3. Do not open the foil pouch until ready to conduct the test.
4. Do not use the results of this test as an aid for contraception.
5. Consult a doctor if irregular or unusually long cycles are experienced.
6. 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.
7. Do not use the test kit after the expiration date listed on the box or pouch.
8. The parts of this kit are a matched set and should always be used together.
9. A test device can only be used once. Discard the test after use.
10. Do not use the results of this test as an aid for contraception.
11. The ovulation test should not be used when pregnancy is suspected.

**Questions and 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 Medical Practitioner 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. **Today’s control band is a different shade of red than yesterday’s control band. Is this a concern?**
   - No. 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. Do not compare bands from different devices.
5. **Can test results be interpreted after five minutes?**
   - No. Test results must be read at 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 minute testing period and then discard the test to avoid confusion.

6. **A pink background color and vertical streaking appeared in the result area during the testing period. Is this a concern?**
   - No. 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**


The BodyTalk® range of products are available at: www.mybodytalk.com.au and include:

- Early Pregnancy Tests - InStream
- Early Pregnancy Tests - Quick Strip
- Pregnancy Planning Kit
- Arm Blood Pressure Monitor
- Wrist Blood Pressure Monitor
- Electronic Pulse Massager (TENS)
- Foetal Heartbeat Monitor

**Questions or comments:** If you have any questions about the instructions or your test results, please refer to the www.mybodytalk.com.au website or call our Consumer Information line on (03) 8892 4803 (during business hours), or write to ACS International Pty Ltd at the address listed below.

Made in China for, and imported and marketed by: ACS International Pty Ltd, P O Box 230, Kerrimuir VIC 3129, Australia.