



One Step Ovulation Test

1071-6 or 1071-10

May 2014



EZ-LH™ One Step Ovulation Predictor Kit

- Please read all the information in this pamphlet before performing the test.
- Keep out of reach of children.
- Check expiration date on each cassette pouch prior to use.
- Store refrigerated or at room temperature 38° - 86°F (3° - 30°C).
- This test cannot be used for contraception.
- For in vitro diagnostic use.

Introduction

EZ-LH™ One Step Ovulation Predictor Kit is a fast, accurate, and convenient method to determine when a woman will ovulate, the most likely time for conception to occur.

What is Ovulation?

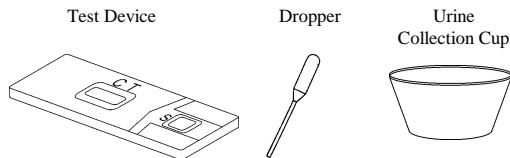
Ovulation is the release of an egg from a woman's ovary. When a woman is about to ovulate, her body releases a large amount of a hormone called LH (luteinizing hormone). Ovulation usually occurs 24 to 48 hours after this surge of LH. EZ-LH™ One Step Ovulation Predictor Kit detects the LH surge by measuring LH in urine. If the surge is present, ovulation is likely to occur in the next 24 to 48 hours.

The presence of an LH surge means that it is likely that ovulation will occur. It does not ensure that ovulation will occur nor does it always indicate that ovulation will occur in the next 24 to 48 hours.

Kit Contents

- (6) Sealed foil packs. Each foil pack contains:
 - Test Device
 - Urine Dropper
 - Desiccant. (This packet should be discarded)
- (6) Urine Collection Cups

Note: Cat.#1070-10 contains 10 sealed foil packs and 10 urine collection cups.



When to Test

To find out when to begin testing, you should determine the length of your menstrual cycle. The length of your cycle is from the beginning of one period to the beginning of the next (count the first day of bleeding as day 1). Determine the usual length of the menstrual cycle over the last few months. Then, refer to the cycle chart below to determine on which day of the menstrual cycle to begin testing.

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

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.

Sample Calendar

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

3 = The first day of menstrual bleeding.

12 = The day to begin testing (Day 10).

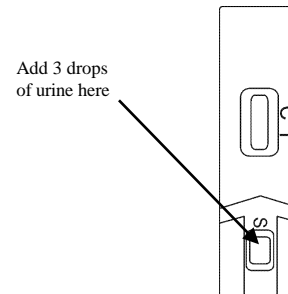
Note: If your cycle length is irregular, that is, if it varies by more than a few days each month, count your shortest cycle length within the past 6 months. Use the chart to work out the day you should begin testing. If you have questions about your cycle length, or if your cycle is not shown on the chart, contact your physician for assistance.

Collect Urine

Collect the urine sample using the urine cup included with this kit. Use a new cup each day. You can collect your urine at any time of the day, but you should try to collect your urine at about the same time each day. Do not collect your first morning urine after waking up. It is a good idea to reduce your liquid intake for about 2 hours before collecting your urine. The urine sample may be stored at room temperature (15°-30°C) 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 within four hours after the collection.

How to Use The Test

1. Remove the Test Device and Dropper from the foil wrapper.
2. Fill the dropper with urine and hold it above the sample well (S) as shown. Add exactly 3 full drops of urine. Allow each drop to soak in before adding the next.
3. Read results at exactly 5 minutes after adding the last drop of urine.



How to Read Your Results

After each test, you must decide if you are having an LH surge.

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.

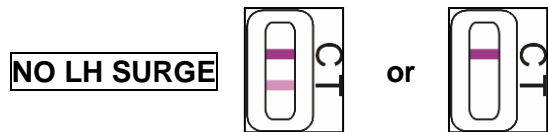
1. POSITIVE FOR THE LH SURGE

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 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) test device.



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 at a later date, 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 an LH surge may not be detected.

1. The concentration of LH is too low to be accurately detected.
2. Testing is performed too early or too late in the menstrual cycle.
3. Testing is stopped before the surge occurs, and should have been continued for a few more days.
4. An LH surge did not occur during this menstrual cycle.

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 an 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.

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. **Once I see a positive result, when is the best time to have intercourse?** Ovulation usually follows the start of the LH surge within 24 to 48 hours. Therefore, it is best to act on the information as soon as possible. You may want to check with your doctor for advice that is right for you.
5. **Today's control band is a different shade of red 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 on the day the test is performed.
6. **Can test results be interpreted after five minutes?** No. Test results must be interpreted within 5 minutes. Although 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 exactly 5 minutes 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 rose background color but will not affect the test results. As long as the control band appears within five minutes, the test is working properly.

8. **What is the clinical performance of EZ-LH?**
Clinical studies for EZ-LH were performed using 947 clinically confirmed samples. EZ-LH showed an Accuracy of 98.3%, Specificity of 98.5%, and Sensitivity 95.9%. This test is designed with a cut-off level of 30 mIU/ml LH.

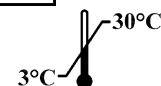
	Storage Temperature	EC REP	Authorized Representative
LOT	Lot Code		Caution, see instructions
	Expiration	IVD	For in vitro diagnostic use
	Manufacturer	REF	Catalog No.

FOR TECHNICAL ASSISTANCE IN THE U.S.,
CALL: 800-854-3002

Ordering Information:

Catalog No. 1071-6 or 1071-10
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IVD



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