

## Easy Prediction One Step Ovulation Test

### Package Insert

REF FLH-103 English CE 0197

For Self Testing

#### PRINCIPLE

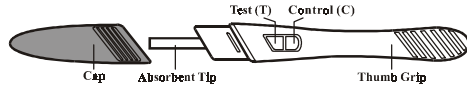
Ovulation is the release of an egg from the ovary. The egg then passes into the fallopian tube where it is ready to be fertilized. In order for pregnancy to occur, the egg must be fertilized by sperm within 24 hours after its release. Immediately prior to ovulation, the body produces a large amount of luteinizing hormone (LH) which triggers the release of a ripened egg from the ovary. This is known as an "LH surge", and usually takes place in the middle of the menstrual cycle. It is during this fertile time that pregnancy is most likely to occur. It is important to note that an LH surge and ovulation may not occur in all cycles.

The Easy Prediction One Step Ovulation Test is a rapid, one-step lateral flow immunoassay for the qualitative detection of LH surges in urine, signaling that ovulation is likely to occur in the next 24-36 hours. The test utilizes a combination of antibodies including a monoclonal LH antibody to selectively detect elevated levels of LH. The assay is conducted by urinating on the Absorbent Tip or immersing the Absorbent Tip in urine, and obtaining the result from the colored lines.

#### PRECAUTIONS

Please read all the information in this package insert before performing the test.

- Do not use after the expiration date printed on the foil pouch.
- Store in a dry place at 2-30°C or 36-86°F. Do not freeze.
- Do not use if pouch is torn or damaged.
- Keep out of the reach of children.
- For *in vitro* diagnostic use. Not to be taken internally.
- Do not open the test foil pouch until you are ready to start the test.
- The used test should be discarded according to local regulations.



#### KIT CONTENTS

- Test midstreams
- Package insert

#### INSTRUCTIONS

##### WHEN TO START TESTING

This kit contains 5 tests, allowing you to test over several days to find your most fertile time. Calculate when to start testing using the chart below.

- First, determine your **Menstrual Cycle Length**. Your Menstrual Cycle Length is the number of days from the first day of your period (menstrual bleeding) to the last day before the next period starts.
- Next, determine the **Days to Count Ahead** after the period to start testing. Find the menstrual cycle length on the first row of the chart below, and read the corresponding number in the second row. This is the number of days after your period to begin testing.
- See the Example and Sample Calendar below to determine which day you should begin testing. First morning urine should NOT be used when testing for LH. For best results, you should test around the same time each day. You should reduce your liquid intake approximately 2 hours prior to testing.

When to Start Testing Chart

Menstrual Cycle Length	21	22	23	24	25	26	27	28	29	30	31	32	33	34	35	36	37	38	39	40
Days to Count Ahead	4	5	6	7	8	9	9	9	9	10	10	10	12	13	14	15	16	17	18	19

Sample Calendar

S	M	T	W	T	F	S
	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	29	30	31			

**Example:** My usual cycle length is 28 days. My last period started on the 3<sup>rd</sup>. The "When to Start Testing Chart" shows that I will count ahead 9 days beginning with the 3<sup>rd</sup>. When I count 9 days ahead on the calendar, I find that I will collect and test my urine starting on the 11<sup>th</sup>.

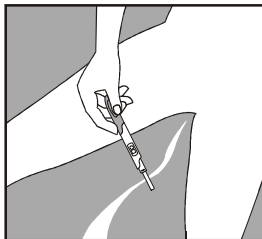
○ First day of the last period

□ Begin testing with the Easy Prediction One Step Ovulation Test

##### DIRECTIONS FOR USE

Determine the day you will begin testing using the "When to Start Testing Chart".

- Bring the pouch to room temperature before opening it. Remove the midstream test from the sealed pouch and use it as soon as possible.
- Remove the **Cap** and place it over the **Thumb Grip**. (See the illustration above)
- Hold the midstream test by the capped **Thumb Grip** with the **exposed Absorbent Tip pointing downward directly into your urine stream for at least 10-15 seconds** until it is thoroughly wet. (See illustration at right)



**Note:** Do not urinate on the **Test** and **Control** windows. If you prefer, you can urinate into a clean and dry container, then dip only the **Absorbent Tip** of the midstream test into the urine for 10-15 seconds.

- After removing the midstream test from your urine, immediately replace the **Cap** over the **Absorbent Tip**, lay the midstream test on a flat surface with the **Test** and **Control** windows facing upwards, and then begin timing for 5 minutes.

- As the test begins to work, you may notice a light red flow moving across the **Test** and **Control** windows. **Read the result at 5 minutes**. If no result appears, wait one minute longer. Do not read the result after 10 minutes.

#### READING THE RESULTS



##### POSITIVE

Two colored lines are visible, and the line in the Test Window (T) is the same as or darker than the line in the Control Window (C). This indicates that you will probably ovulate in 24-36 hours.

##### NEGATIVE

Two colored lines are visible, but the line in the Test Window (T) is lighter than the line in the Control Window (C), or there is no line in the Test Window (T). This indicates that no LH surge has been detected and daily testing should be continued.

##### INVALID

Control line fails to appear. The result is invalid if no colored line appears in the Control Window (C), even if a line appears in the Test Window (T). You should repeat the procedure with a new test midstream.

#### LIMITATIONS

There is the possibility that this test may produce false positive or false negative results. Invalid results are most likely caused by not following the instructions properly. Review the instructions and repeat the test with a new test midstream. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

#### QUESTIONS & ANSWERS

- Q: Can I use the Easy Prediction One Step Ovulation Test to avoid pregnancy?**  
A: No, the test should not be used as a form of birth control.
- Q: How accurate is the Easy Prediction One Step Ovulation Test?**  
A: A clinical evaluation was conducted comparing the results obtained using the Easy Prediction One Step Ovulation Test to another commercially available urine membrane LH test. The in-house clinical trial included 150 urine specimens. The results demonstrated >99.9% specificity and >99.9% sensitivity with an overall accuracy of >99.9%.
- Q: How sensitive is the Easy Prediction One Step Ovulation Test?**  
A: The Easy Prediction One Step Ovulation Test detects luteinizing hormone (LH) in urine at concentrations of 40 mIU/mL or higher.
- Q: Do alcohol or common medications affect the test?**  
A: No, but you should consult your physician if you are taking any hormonal medication. Also, recent oral contraceptive use, breastfeeding, or pregnancy could affect the test results.
- Q: Why should I not use first morning urine? What time of the day should I perform the test?**  
A: We do not recommend first morning urine because it is concentrated and may give a false positive result. Any other time of day is suitable. For best results, try to collect your urine at approximately the same time each day.
- Q: Will the amount of liquid I drink affect the result?**  
A: Heavy intake of fluids prior to testing will dilute the hormone in your urine. We suggest that you limit your fluid intake for about two hours before you perform the test.
- Q: How long will the lines remain visible?**  
A: The test should be read at 5 minutes for best results. A positive (Surge) result will never disappear. The colored line(s) may become darker and a tinted background may appear after several hours. Some negative results may later display a faint second color line because of evaporation from the test line. Therefore, you should not read the results after 10 minutes, discard the test once you have read the result.
- Q: Once I see a positive result, when is the best time to have intercourse?**  
A: Ovulation is likely to occur within 24-36 hours. This is your most fertile time. Sexual intercourse within this time frame is advised.
- Q: I am now using the basal body temperature method (BBT). Does this test replace BBT?**  
A: The Easy Prediction One Step Ovulation Test does not replace the BBT method. The shift in basal body temperature primarily indicates that ovulation has already occurred. The Easy Prediction One Step Ovulation Test indicates that ovulation is about to occur.
- Q: I received a positive result and had intercourse during these fertile days but I have not become pregnant. What shall I do?**  
A: There are many factors that can affect your ability to become pregnant. It can take normal, healthy couples many months to achieve a pregnancy and often you may need to use the test kit for 3-4 months before achieving pregnancy. If pregnancy is not achieved after 3-4 months, you and your partner should consult your physician.
- Q: I have had a positive result and had intercourse during these fertile days. I think I may be pregnant. How soon can I find out?**  
A: Our Early Detection One Step Pregnancy Test can provide you with results as early as the first day of your missed period.

#### Index of Symbols

	Attention, see instructions for use		Tests per kit		Manufacturer
	For <i>in vitro</i> diagnostic use only		Use by		Do not reuse
	Store between 2-30°C		Lot Number		Catalog #

Manufacturer  
ACON Laboratories, Inc.  
4108 Sorrento Valley Boulevard,  
San Diego, CA 92121, USA



"Auth. Rep."  
acc.to IVD 98/79/EC  
MDSS  
Burkhardtstr. 1  
30163 Hannover, Germany

Number: 1150125202  
Effective date: 2004-4-26