



LH Ovulation Rapid Test Dipstick (Urine) Package Insert For Self-testing

REF FLH-101H English

A rapid test for the qualitative detection of luteinizing hormone (LH) in human urine.

INTENDED USE

The LH Ovulation Rapid Test Dipstick (Urine) is a rapid chromatographic immunoassay for the qualitative detection of human luteinizing hormone (hLH) in urine to aid in the detection of ovulation.

SUMMARY

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.

PRINCIPLE

The LH Ovulation Rapid Test is a rapid lateral flow immunoassay for the qualitative detection of hLH surges in urine, signaling that ovulation is likely to occur in the next 24-36 hours.

The urine sample moves forward laterally on the test due to capillary forces. In the presence of hLH an immunological reaction between hLH and labeled anti-hLH antibodies takes place leading to a distinct colored test line.

REAGENT

The test contains anti-LH particles and anti-LH antibody coated on the membrane.

SPECIMEN COLLECTION AND PREPARATION

- Determine the optimal time for urine collection. For best results, collect urine at about the same time each day.
Reduce liquid intake approximately 2 hours prior to urine collection.
Record the date, cycle day and time of urine collection.

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.
Do not use if pouch is torn or damaged.
Store in a dry place at 2-30°C or 36-86°F. Do not freeze.
Keep out of the reach of children.
Do not open the test foil pouch until you are ready to start the test.

STORAGE

Store as packaged at room temperature or refrigerated (2-30°C). The test is stable through the expiration date printed on the sealed pouch.

MATERIALS

- Materials provided: 1. Test Dipsticks; 2. Package Insert;
Materials required but not provided: 1. Specimen Collection Containers; 2. Timer

INSTRUCTIONS

WHEN TO START TESTING

Calculate when to start testing using the chart below.

- 1) 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.
2) Next, determine the Days to Count Ahead after the period to start testing.
3) If your cycle is shorter than 21 days or longer than 38 days, consult your doctor.

When to Start Testing Chart

Table with 2 rows and 18 columns: Menstrual Cycle Length (Days to Count Ahead) vs Days to Count Ahead.

Example: My usual cycle length is 28 days. My last period started on the 3rd. The "When to Start Testing Chart" shows that I will count ahead 11 days beginning with the 3rd.

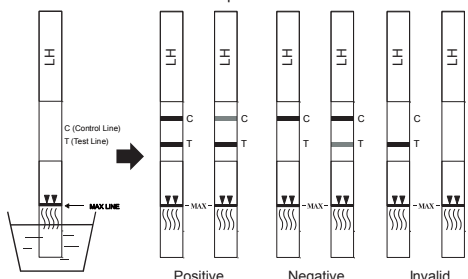
Sample Calendar

Sample Calendar grid showing days of the month with circled numbers 3, 10, 17, 24, 31.

- First day of the last period
Begin testing with the LH Ovulation Rapid Test

DIRECTIONS FOR USE

- Determine the day you will begin testing using the "When to Start Testing Chart".
1. Allow the test and urine specimen to reach room temperature (15-30°C) prior to testing.
2. Bring the pouch to room temperature before opening it.



READING THE RESULTS

POSITIVE: Two lines are visible and the line in test line region (T) is the same as or darker than the line in the control line region (C).
NEGATIVE: Two lines are visible, but the line in the test line region (T) is lighter than the line in the control line region (C), or there is no line in the test line region (T).

INVALID: Control line fails to appear. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure.

QUALITY CONTROL

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

A negative result indicates that no LH surge has been detected and daily testing should continue. Not every woman ovulates mid-cycle, therefore, a positive result may not appear during the selected days of testing.

LIMITATIONS

- 1. For self-testing in vitro diagnostic use.
2. This test may not be used as a form of birth control.
3. Do not reuse the tests.
4. The test results should not be affected by pain relievers, antibiotics and other common drugs.

EXTRA INFORMATION

- 1. Q: When can I do the test? A: After you determine the best day to start testing based on your monthly cycle...
2. Q: Can I use the LH Ovulation Rapid Test to avoid pregnancy? A: No, the test should not be used as a form of birth control.
3. Q: How accurate is the LH Ovulation Rapid Test? A: A clinical evaluation was conducted comparing the results obtained using the LH Ovulation Rapid Test to another commercially available urine LH test.

- 5. Q: I have tested for several days and I did not see a surge. What do I do? A: Since every woman does not always ovulate at mid-cycle, you may not detect the hLH surge in the first seven days of testing.
6. Q: I have tested for 8 days or more and I still did not see my hLH surge, what is wrong? A: About 90% of ovulating women with regular cycles will see their surge during 8-10 days of testing.
7. Q: I have used the ovulation test for three months, and each month I have seen a surge and have had intercourse that day or night. I have not become pregnant yet. What is wrong? A: First, it is important to remember that it can take normal, healthy couples many months to become pregnant.

TEST RESULTS CHART

Table with 4 columns: Test, Date, Collection Time, Result. Rows for Day 1 through Day 5.

BIBLIOGRAPHY

1. Elkind-Hirsch, K; Goldzieher, JW; Gibbons, WE and Besch, PK. Obstetrics and Gynecology, 67(3): 450-453, 1986.

Index of Symbols

Table mapping symbols to instructions: Consult Instructions For Use, Store between 2-30°C, Do not use if package is damaged, Tests per kit, Use by, Lot Number, Manufacturer, EC REP, Authorized Representative, Do not reuse, REF, Catalog #.









