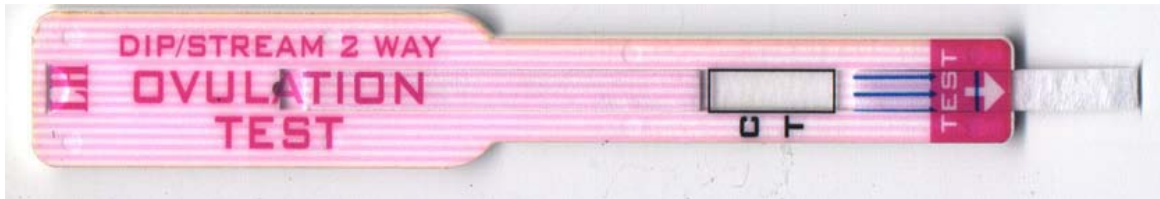


HEALTH-CHEM DIAGNOSTICS LLC

3341 SW 15TH ST – Pompano Beach, FL 33069 – USA - Tel: (954) 979-3845 – Fax: (954) 979-7997 –
Website: www.healthchemdiagnostics.com



PLEASE READ ALL INSTRUCTIONS CAREFULLY BEFORE BEGINNING

The LH Test (Ovulation Predictor):

- An easy to use ovulation predictor test
- Results are available within 3-10 minutes
- Improved sensitivity allows early detection of LH at 25 mIU/ml or greater
- Precise and accurate laboratory test findings with an accuracy between 99% and 100%

Kit Description and Use:

The LH Test monitors the amount of luteinizing hormone (LH) in your urine. Normally, during each cycle, the level of LH will suddenly increase (this is called LH surge), causing the release of an egg from the ovary within 24-40 hours. This process is known as ovulation. Follow these instructions and you should know when you are most able to become pregnant.

The LH test is designed to detect LH levels at or greater than 25 mIU/ml.

Please note: LH surge and ovulation may not occur in all cycles. Menstrual bleeding that begins at the expected time is not always a sign that you have ovulated.

This kit contains all the supplies required to determine the LH surge over a period of five (5) days.

When to Start Testing:

Determine the length of your normal 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). If your cycle length is irregular, that is, it varies by more than a few days each month, count your shortest cycle length within the past six (6) months. Use the Chart provided to determine when you should begin testing.

Test Principles:

The LH Test is an immunochromatography based in vitro assay. The Control Band assures the proper function of the test. This test is designed for the determination of human Luteinizing Hormone

Your usual cycle length and day of cycle to start testing:

Cycle Length	Day of Cycle to start testing	Cycle Length	Day of Cycle to start testing	Cycle Length	Day of Cycle to start testing
21 days	Day 4	28 days	Day 11	35 days	Day 18
22 days	Day 5	29 days	Day 12	36 days	Day 19
23 days	Day 6	30 days	Day 13	37 days	Day 20
24 days	Day 7	31 days	Day 14	38 days	Day 21
25 days	Day 8	32 days	Day 15	39 days	Day 22
26 days	Day 9	33 days	Day 16	40 days	Day 23
27 days	Day 10	34 days	Day 17		

Two magenta bands will appear on the READ AREA of the predictor, one is a Control Band and the other a Test Band. The Control Band serves as a reference of the color intensity. If the Test Band does not appear or is lighter than the Control Band, you have not begun your LH surge. You should continue to test daily.

If the Test Band is darker than the Control Band, you have detected your LH surge. You should ovulate within the next 24-40 hours. Once you have detected your surge, you can stop testing for this cycle.

After you have read your results, the predictor should be discarded.

Once you know that you are about to ovulate, you know you are at the start of the most fertile time of your cycle. If you have sexual intercourse at any time during this time period, you are likely to maximize your chance of becoming pregnant.

The LH Test is an immunochromatography based in vitro assay. The Control Band assures the proper function of the test. This test is designed for the determination of human Luteinizing Hormone (LH) in urine, to predict the time of ovulation in women, thereby identifying the time in your cycle when you are the most fertile and are most likely to become pregnant.

Urine Collection and Storage:

For best results, try to collect urine at about the same time each day. You should not have urinated for at least 4 hours prior to testing.

Do not collect your first morning urine.

Collect your urine once a day in the collection cup provided. Six cups are included. Use a new collection cup for each test.

If you do not test immediately, you may store your urine in a clean, dry, glass or plastic container for up to eight (8) hours at room temperature or in the refrigerator (2-8°C or 35-46°F) for up to 72 hours. Do not freeze.

If you refrigerate your urine, let it reach room temperature before testing (approximately 15 or 20 minutes). After testing is completed, dispose of excess urine into the toilet and discard the predictor into the trash.

Kit Contents:

1. Five (5) individually packaged LH predictors
2. Five (5) urine collection cups
3. Directions for use in both English and Spanish

Storage and Stability:

The predictor can be stored at room temperature (15-30°C or 59-86°F) in the sealed pouches through the expiration date. Do not open the pouch until ready to test.

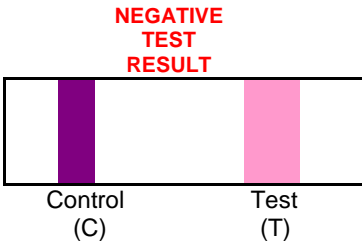
Instruction for Use:

1. Remove a (1) LH predictor from its foil pouch by tearing at the "notch". Do not open the pouch until ready to test.
2. Collect your urine in one (1) of the six (6) collection cups provided.

Alternatively, you may dip the wick end of the test device in the urine stream for approximately six (6) seconds.

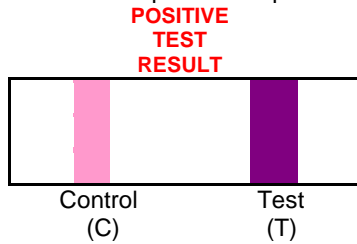
Interpretation of Results:

Two bands will appear in the READ AREA of the predictor. The band closer to the top pad on the predictor is the CONTROL BAND. The other band is the TEST BAND (closer to the white pad on the predictor).



TEST BAND has no color or the color is lighter than the CONTROL BAND

Your LH is at Basal Level.

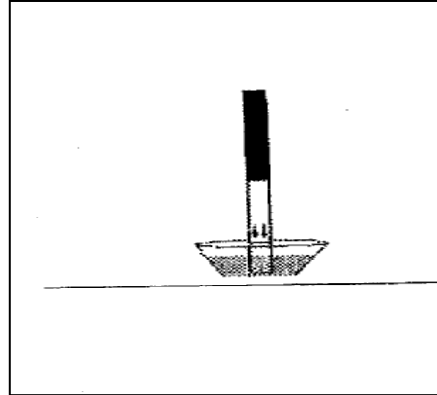


TEST BAND is darker than or equal to that of the CONTROL BAND.

A POSITIVE RESULT -

INDICATING LH SURGE. Once you have detected your surge, you can stop testing for this cycle. You are likely to ovulate within 24-40 hours.

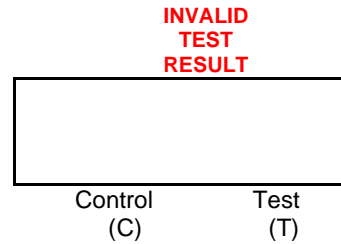
3. Fill test performance cup to line marked on side. Discard excess urine in toilet.
4. Carefully place the LH predictor, white end of the strip, into the test performance cup, as shown. Hold the strip in the cut for 5 seconds.



5. Remove the strip from the test performance cup and lay the strip on a flat surface, pad and arrow side facing upward.
6. Wait for five (5) minutes, but no longer than ten (10) minutes, before reading the test results.
7. When finished testing, discard urine sample from performance cup into toilet, rinse, dry and keep for next

OVULATION AND FERTILITY

Ovulation normally takes place once a month, about two (2) weeks before the start of your period. This means that a single egg



When neither TEST BAND nor the CONTROL BAND appears on the READ AREA Portion of the predictor, the test is invalid. Call 1800-482-2907.

If there is no CONTROL BAND, the test is also invalid

RECORD YOUR TEST RESULTS ON THE CHART PROVIDED.

matures in one of your ovaries and is released to travel down the fallopian tube to the uterus. Pregnancy can only occur when the egg is mature and is in the fallopian tube where it can be fertilized by the sperm. The egg is only like that for about twenty-four (24) hours – your most fertile time only lasts for a short time each month.

Your partner's sperm can usually stay active to fertilize the egg for a maximum of seventy-two (72) hours. To maximize your chances of becoming pregnant, you should have intercourse during your most fertile time, 1-3 days immediately after you detect your LH surge.

It is important to know and understand that LH surge and ovulation may not occur in all cycles. Menstrual bleeding that begins at the expected time is not always a sign that you have ovulated.

TEST RESULT CHART

Test #	Collection Date	Cycle Day	Collection Time	Test Results (NS or S*)
1				
2				
3				
4				
5				

- NS = No Surge present, basal LH level, NEGATIVE RESULT
- S = Surge of LH level present, POSITIVE RESULT

REASONS FOR NEGATIVE RESULTS:

1. First morning urine should not be used when testing for LH.
2. The amount of LH in your urine may be too low.
3. You may have tested too early or too late in your cycle.
4. You may not have had an LH surge during this cycle.

WHEN TO STOP TESTING:

Unless otherwise specified by your doctor, you can stop testing once you have detected your LH surge. The leftover tests maybe used for your next cycle. But remember that you may need to test for five days in a row to detect your LH surge.

LIMITATIONS:

- You must follow the directions carefully to get accurate results.
- Do not open a foil pouch until you are ready to perform the test each day (just before adding to urine sample).
- The results of this test cannot be used as an aid for

contraception.

- Consult your physician if you have irregular or unusually long cycles.
- You should not use this test if you are pregnant, menopausal, or after hCG therapy (injection).
- Do not use this kit after the expiration date printed on the package.
- Once a predictor has been used, discard in a proper waste container.
- Never reuse a predictor.
- **The Test Kit is for In Vitro Diagnostic Use Only**

Questions & Answers

Q. Should I restrict my diet?

A. No

Q. Does alcohol, aspirin or any other common drug affect the test?

A. No, but you should consult your physician if you are taking any hormonal medication.

Q. Can I use the LH Test for contraception?

A. No. The test detects LH surge, which begins only 24-40 hours before you reach peak fertility. Since sperm can survive for 72 hours or more, you could still become pregnant if you have had sexual intercourse within several days before the time of peak fertility.

Q. Why can't I use the first morning urine sample?

A. If you use the first morning sample, you may miss the real first day of your LH surge because your urine is concentrated during sleep and the concentrated urine may give you a false positive result. The best time to perform this test is between 10 am and 8 pm. Be sure to collect at about the same time each day.

Q. I noticed that today's control band was a different shade of red than yesterday's control band. Should I be concerned?

A. Variations in the control band will not affect the Test Result. You always compare your Test Result to the Control Band on the day you perform the test.

Q. Do I need to compare my daily readings?

A. No, each daily reading tells you whether or not you are about to ovulate. If the test line is similar to or darker than the control band, then you know you have detected your LH surge.

Q. Do I need to use all 5 tests?

A. No, you can stop testing when you detect your LH surge and save the remaining tests to use next month.

Q. What could interfere with my test results?

A. If you are pregnant, have recently been pregnant or have reached menopause, you may get a misleading result. This may also be true if you are taking drugs, such as Danocrine, or injections containing hCG (e.g. A.P.L. or Profast) or LH (e.g. Pergonal), all of which affect the outcome of this test, so check with your doctor before testing. Clomid (Clomiphene Citrate) does not affect the result of your testing.

Q. Will oral contraceptives affect the results?

A. After using the pill, your cycles can be irregular and may take some time to stabilize again. In those circumstances, you may need to use more than one LH kit each cycle or you may want to wait until you have had 2 normal menstrual cycles before starting to use the LH Test. However, you should follow your doctor's advice as to when you should try to conceive.

Q. Can I be sure of getting pregnant by using the LH Test?

A. The LH Test is a simple, effective way of pin-pointing when you ovulate and thereby define the time each month when you are most fertile. There are many reasons why you may not conceive, even if you have been able to time intercourse during your most fertile time. It is important to remember that it often takes normal healthy couples many months to become pregnant. If after several months you have no success, consult your doctor. Since you have been monitoring your LH surge, you will be able to give your doctor a clear picture of how you have been ovulating.

Q. I've used all 5 tests as instructed, but I have not yet detected my LH surge.

A. The 5 tests contained in the LH kit are sufficient for many women with regular cycles. However, if your cycle is irregular (varies by fewer than 3 days), you may need to use additional LH Tests to predict the time of peak fertility. Ten days of testing should pick up the LH surge in about 90% of women.

Q. How do I know that the Test has worked correctly?

A. You should see two (2) magenta bands in the READ AREA. The first line is the TEST BAND which measures the concentration of LH relative to 25 mIU/ml and the second band is the CONTROL BAND that tells you the test is working properly. If you do not see the two bands, the call the Technical Help Line at 1-800 -482-2907.

Manufactured in the USA by:
HEALTH-CHEM DIAGNOSTICS LLC,
POMPANO BEACH, FLORIDA
Website: www.healthchemdiagnostics.com

CUSTOMER HOT-LINE: 1-800-482-2907

