

SERATEC® LH MAX Ovulation Test

REF LH-C1

Semi-quantitative membrane test for the in-vitro detection of LH (luteinizing hormone) in urine

A one step, 5 minute test at room temperature for self-testing

Background

A woman's body continuously produces a small amount of luteinizing hormone (LH). During the middle of the menstrual cycle, there is a sudden increase of this hormone followed by a rapid decline back to basal levels. While the maximal LH concentration before and after the surge is < 20 mIU/ml, LH levels from >30 to 100 mIU/ml are reached at peak times. This increase of the LH level, called LH surge, promotes the release of a mature egg from the ovary (ovulation). For most women, ovulation will occur within 24 - 36 hours after the first steep increase of the LH level. Immediately after the ovulation the egg is ready to be fertilised for a short time (appr. 12-24 hours). With SERATEC® LH MAX, LH in urine will be determined for a time period of 5 days. In this time the test will detect if and when a LH surge occurs. The „most fertile days“ of the menstrual period start after this LH surge. As sperms are fertile for about 3 days (rarely even 6 days) after sexual intercourse the fertile period can be limited to about 3-5 days before and 2 days after the surge.

Principle

The SERATEC® LH MAX is a rapid test for the determination of human luteinizing Hormone (LH) in urine. When LH is present in the sample, it is bound by specific antibodies immobilised at the test region of the membrane. This complex is then made visible by binding of another gold-labelled antibody, resulting in a colored line. The intensity of the test result line depends on the amount of LH in the urine sample.

Starting Day of Testing

The starting day of testing (total 5 days) depends on the length of the last normal menstrual cycles. The first day of bleeding of menstrual period is counted as day 1. The chart below demonstrates the correlation between starting day and the length of a typical menstrual cycle.

cycle length days	begin testing on
26 or 27	10th day of cycle
28 or 29	11th day of cycle
30 or 31	12th day of cycle
32 or 33	13th day of cycle

If the menstrual cycle is shorter or longer than in the chart above, a physician should be consulted for the recommended day to start testing. If your cycle is not

regular it might be necessary to prolong the testing period.

1) Preparation

- If the test has been stored refrigerated it should be brought to room temperature prior to testing.
- A clean (free of detergent) and dry glass or plastic container for collecting the urine and a watch should be prepared

For each day of testing one test device still sealed in the pouch is required.

2) Collection of samples

The urine samples should be collected at around the **same time** each day. Morning urine can be used for testing, but please note that LH might accumulate in the urine over the night thus the possibility of a false positive single test is a little increased. An excess uptake of liquid should be avoided at least 3 hours before sample taking (dilution of the urine). If necessary the sample can be stored in the refrigerator for up to 24 hours. Before testing the sample must be warmed to room temperature.

3) Test procedure

- Carefully read instruction leaflet.
- Take one test, open the pouch, and remove the test device and the pipette. Place the device on an even surface. Once opened the test should be performed immediately.
- Withdraw some urine from the container with the pipette and dispense **5 drops** into the **round sample well**. You can see how the pink liquid front starts to move across the membrane of the test region.
- Wait exactly for 5 minutes. During this time one or two red colored lines will appear.
- Read the result **immediately**. Note the result together with the date and the sample collection time in the table (page 3).

4) Interpretation of results

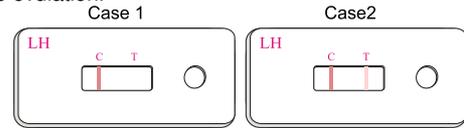
The interpretation will be done by comparing the red colored lines that will appear under the mark „T“ (test result line) and the mark „C“ (control or reference line) in the test region. The color intensity of the test result line (T) depends on the amount of LH in the urine sample.

Case 1: The test result line (T) does **not** appear; the control line (C) is present.

Negative result: The LH level in the urine sample is such low that it will not be detected by the test. This case is typically observed before the LH surge.

Case 2: The color intensity of the test result line (T) is **less intense** than that of the control line (C).

Negative result: The LH level will be detected by the test, but is below the level of the LH surge. Like case 1 this result will be observed in the time before ovulation.



Case 3: The color intensity of the test result line (T) is equal to that of the control line (C).

Positive result: The LH level is likely at or around the surge level and ovulation will be expected within the next 24-36 hours. (see remark)

Case 4: The color intensity of the test result line (T) is more intense than that of the control line (C).

Positive result: Like case 3 the LH level is likely at or around the surge level and ovulation will be expected within the next 24-36 hours. (also see remark)

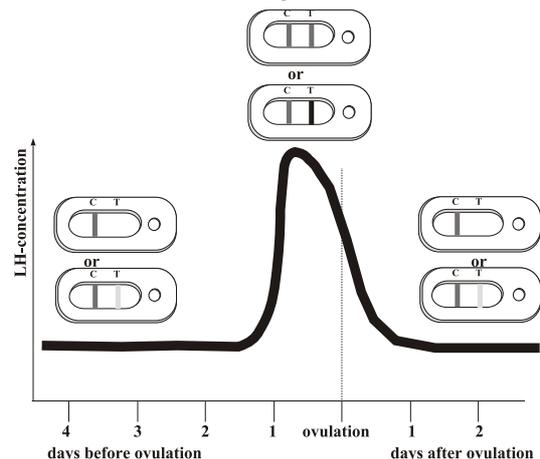


Remark:

The individual LH level of the LH surge differs. This means that for one woman case 3 already shows the maximum of the LH surge, for another woman it is case 4.

For the prediction of the ovulation the first occurrence of case 3 or case 4 is important. After the first positive test result ovulation should occur within 24-36 hours.

For a better understanding of the interpretation of the test results, the typical LH levels and the corresponding test results in the days before and after ovulation are shown in figure below.



Invalid results:

After 5 minutes no control line appears in the test region. In this case the test is invalid even if the test result line has appeared.



Try to repeat the test with a new test device and the same urine sample. Make sure that you add a sufficient amount of urine. If the test shows again an invalid result, the components of the test do not function correctly. In this case stop testing and repeat the test series in the next menstrual cycle with a new test kit.

For your safety:

- Not to be taken internally.
- Keep out of reach of children.
- Do not use test after the expiration date.
- Do not use test if the pouch has been damaged.
- The potentially infectious materials of the test (e.g. antibodies) do not cause any hazard if the device is used according to the instructions.
- Please follow instructions carefully.

Important information

- * Keep strictly to the instructions provided in order to get reliable test results.
- * The results of this test cannot be used as an aid for contraception.
- * The test should not be used:
 - during or shortly after pregnancy
 - during/after the onset of menopause (constantly increased LH level)
 - after or during hormone treatment
- * The use of "the pill" may interfere with correct test results.
- * The menstrual cycle can be irregular after discontinued use of "the pill" or a previous miscarriage. There should be at least two regular menstrual cycles before testing.
- * Some diseases (e.g. polycystic ovaries, hormonal imbalance) can falsify the results of the test. In this case a physician should be consulted.

- * Avoid excess liquid intake during testing since it may dilute the amount of LH in the urine and could falsify the result.
- * Wash your hands after testing.
- * After use, the test device can be put into the normal waste.
- * The test should be stored at room temperature below 30 °C or in the refrigerator (2-8 °C)

Specificity of the test

The structurally related hormones hCG (human chorion gonadotropin), FSH (follicle stimulating hormone) and TSH (thyroid stimulation hormone) do not interfere with the test result if tested at normal (no pregnancy, no hormone treatment) physiological concentrations. The intake of analgesics like acetyl salicylic acid, ibuprofen or acetaminophene does not influence the test result

Accuracy

Studies show that the SERATEC® LH MAX reliably detects the LH maximum with 100% agreement. If you do not get pregnant although you had intercourse during the "fertile days" it could have some normal reasons and you should not worry about it. If you do not become pregnant after several months, you may want to consult your physician.

We wish you a successful testing and good luck with the SERATEC LH MAX!

Your SERATEC team

Short description of the test procedure

1. Collection of the urine sample
check: container is clean
same time of the day
no excess liquid uptake
2. Remove test device and place on even surface.
3. Add five drops of urine into the round sample well
4. Wait exactly for 5 minutes (timer)
5. Interpret test result and note the result in the table.

This description is an aid only and should not replace the detailed description. If you feel unsure or have questions concerning the test procedure or the interpretation of the test results, please review the detailed text.

Table of test results

test	day of cycle	Sample collection		result*
		date	time	
1				
2				
3				
4				
5				

***negative result** (no ovulation expected):

Test result line (T) is not visible **or** the color of the test result line (T) is less intense than that of the control line (C).

***positive result** (ovulation expected within the next 24-36 hours):

Color of the test result line (T) equals control line **or** is more intense than that of the control line (C).

The LH surge may last more than one day. For the prediction of the ovulation the **first day** showing a positive test result is crucial.

Possible questions and answers
I have problems to find out the starting day of the test series. How is it determined?

To determine the start of the test correctly you must know the length of your menstrual cycle. The first day the bleeding start is counted as the first day of the cycle. The cycle lasts until the last day before the next bleeding of the following menstrual cycle occurs. Calculate the length of your cycles for the previous months. If there are slight variations (up to 4 days) take the mean. From the table on the first side of the instruction leaflet you can now see on what day of the cycle the test should begin.

Example: The normal length of your cycle is 28 days. The recommended starting day of the test series is the 11th day of your cycle (see table). Your last period started on June 5th. Take a calendar and count 11 days starting from June 5th. You will see that the test series should be started on June 16th.

Is it necessary to compare the daily readings?

No. The control line (C) shows the same intensity of color for each test, so that each test can be interpreted independently. Each daily reading tells you whether or not you are about to ovulate. If the test result line (T) shows a similar or darker color than the control line (C) you have detected your LH surge. Ovulation should occur within 24-36 hours after the first positive result.

Do I need to use all 5 tests?

No, you can stop testing when you detect your LH surge and save the remaining tests for the next month, if necessary. However, if you are a first-time user, or if you are not sure whether you detected your LH surge, you may want to follow the rise and the fall of the LH level in your urine as depicted in the figure on page 2. This would reassure you in the prediction of the ovulation.

What if the LH surge is not detected?

There are several explanations if you cannot detect an LH surge. One possibility is that you may not have ovulated in the particular month. This may occur occasionally, and it is normal. Another possibility is that you missed your LH surge and that it either occurred before or after the test series. This might be due to an irregular cycle or you may have miscalculated your menstrual cycle. You might want to continue testing with another test kit or start testing earlier in the next month. Also make sure that the urine sample was reliably collected. Different times of the day and irregular liquid uptake may interfere with the result of the test. If you continue to get readings that do not correspond to the expected results, please consult your physician.

Technical data:

Product name: SERATEC LH MAX
 Catalogue-No.: LH-C1
 Content: 5 single sealed Tests containing a plastic pipette, one manual
 Active compounds: monoclonal antibodies against LH
 Material tested: fresh human urine; no special treatment necessary
 Purpose: In-vitro diagnostic device for laymen for the detection of LH in urine
 Test characteristics: lower detection limit: ca. 5 mIU LH/ml
 Color intensity of control line corresponds to ca. 35 mIU LH/ml
 Diagnostic sensitivity: >99%
 Diagnostic specificity: >99%

Storage: The test should be stored in the sealed pouch at room temperature (+4 - +30 °C). After opening the protective pouch the test should be used immediately.

Method of detection: The urine dropped into the sample well is moving by the capillary effect of the test membrane. In the presence of LH an immunological reaction between LH and the antibodies in the test will take place that results in the formation of the red colored test result line (T). Another pair of antibodies that react with each other independently on the presence of LH form the control line (C). By comparison with the test result line the amount of LH in the urine can be estimated. The control line also shows that the test has functioned correctly. This kind of test is known as chromatographic immunoassay.