



OVULATION TEST

Laboquick Ovulation Test User Guide

Intended Use:

Laboquick Ovulation Test is an immunochromatographic based one step quick test that aimed at qualitative detection of human luteinizing hormone (LH) in urine. The test is for in-vitro usage. For Self Testing and home Use.

Product Code: LBOV.02

Summary:

Luteinizing hormone (LH) is always present in human urine. LH rises considerably in women just before the day which is the most appropriate to get pregnant. This is generally called LH surge. This LH rise triggers ovulation and this means that eggs are released from ovaries. Egg can be fertilized only 6 – 24 hour after ovulation happens. Because of that reason determination of ovulation by testing LH rise is so important for the women who likes to get pregnant. Best testing timings are 11 am at morning, 3 and 5 pm afternoon and 10 pm at night. Early morning test cannot give a good result because expected LH values cannot be caught. If LH rise need to be caught test has to be completed in the later times.

Test Principle:

The menopause test device consists of a sample window including a sample pad that the urine is dripped on it. Sample pad is held by a permeable membrane. The membrane consists of three antibody areas. First one of these areas is mobile and the other two are stable. The mobile area includes monoclonal antibodies and color sensitive colloidal gold particles. The stable area that forms the test line includes anti-LH antibodies on the membrane. The third area that forms the control line includes an anti-mouse immunoglobulin. The sample urine that dripped starts to move on the membrane. If the sample includes enough LH in the sensitivity range of the device, anti-LH forms a compound with colloidal gold conjugate and moves towards to the test area that indicated by the letter "T". Then the compound enclosed in this area and thereupon a line is formed in the area "T". Since the line in this area is related to the LH presence in the sample, it is evaluated with the line in the test area and the absence or the presence of this line shows a negative or a positive test result. The colloidal gold particles those are not enclosed in the test area move towards to the control line area and successfully enclosed in the section "C" in order to form control line regardless to the presence of LH. Finally the line that formed in this area acts as a control device by showing that there is enough sample in the device and the sample followed the correct flow course.

When test should be completed:

Test can be completed in any time of the day but it can be done later than 10 am in morning and before 8pm at night. If test will be completed twice in a day, 8 hours should be left between two testing timings will help to catch LH rise. Test should be done at the same times for every repeating day. Liquid intake should be lowered. To find start time of test, normal menstruation cycle period day should be determined. Menstruation period is between the start of first period (first bleeding time) and the time before other start of other bleeding. Count the first day of bleeding and determine this day as first day. If there is menstrual period disorder or it shows more than few days drift on the period take average days of 3 months.

Please use the table below to determine the test starting date.

Normal Menstruation Period (Total Day Number)	Number of day after last menstruation period started	Normal Menstruation Period (Total Day Number)	Number of day after last menstruation period started
21	5	31	14
22	5	32	15
23	6	33	16
24	7	34	17
25	8	35	18
26	9	36	19
27	10	37	20
28	11	38	21
29	12	39	22
30	13	40	23

How LH rise can be realised?

After reading results of each test, decision can be done according to LH rise. If test result is positive, probability LH rise is being seen. If the result is negative LH rise is not being seen. Even LH rise changes dependent to biological factors it can continues 1 to 3 days. If lighter line than control line is seen it is a proof of low level LH in urine.

Package Contents

Two Ovulation Tests, disposable plastic pipettes, silica gel bags as humidifier.

Materials which are necessary for the test but did not included in the package.

Sample Collection Container, chronometer.

Warnings and Cautions

1. Read the instructions before use.
2. Do not ever freeze the tests. If the test was stored in a refrigerator, wait the product reaches to the room temperature before use. The test must be carried out in room temperature (between 15 – 30 degrees).
3. Do not use a test after expiry date.
4. Use only human urine as a sample.
5. Observe carefully the number of drops. Only 2-3 drops must be dripped on the test.
6. After removing the testing device from its package, use it immediately.
7. If the package is torn, the device must not be used.
8. To prevent mixing between samples, use a different disposable sample dosimeter for each test.
9. During the test, no cosmetic application must be done, no liquids or food must be consumed and do not smoke.
10. The device is just for outer body diagnosis.
11. It's a disposable test.

Test Usage Procedure:

1 Collect urine in a clean cup.

2 Be sure that test device is on room temperature.

3 Remove the test from the package just before starting the test. Place the test on a flat surface.



4 Take sample with the help of plastic pipette.

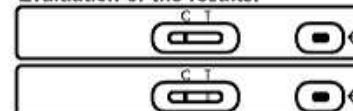


5 Drop 3 - 4 drops of urine sample in to the sample cavity. Any air bubble occurrence must be prevented.



6 Test will work and result will be taken in 5 minutes. Do not take any results occur after 10 minutes into consideration.

Evaluation of the results:



NEGATIVE

On Result Window Line at C region Shows Negative Result. If there are two lines both on "C" and "T" region and if "C" line is darker than "T" line so the result can be read as negative.



POSITIVE

On Result Window, lines at both "C" and "T" region with same darkness Show positive result. If there are still two lines both on "C" and "T" region, and if "T" line is darker than "C" line so the result can be read as positive.



INVALID

If there are no lines on the result window after the 15 minutes, the result is invalid. The test must be re-done with a new test kit.

Sensitivity: The test can detect 25mIU/ml LH in urine.

When can testing stopped?

There is no need to make another test after determination of LH rise unless doctor gives opposite decision.

Storage Conditions:

The tests must be stored between +4 to +30°C and must not be frost. Under these conditions, the device work stably until the expiry date that printed on the packaging unless the package is opened.

Collecting and preparing the sample:

1. The urine sample must be collected in a clean and dry plastic or glass container without any additives or preservatives.
2. The sample that were taken can be used in room temperature in only 24 hours period.

Test Limitations:

1. This test is designed for using human urine only.
2. Any false positive result can be possible because of the materials in urina and personal test usage faulties.
3. This tests results are not sufficient to put exact diagnosis. Final test result should be done by a doctor.

References:

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Manufacturer:

Köroğlu Tibbi Matz. San. ve Tic. Ltd. Şti,

1776/23 Sok. No:4/A Mevlana Mah.

Bornova-İzmir-Turkey

Tel: +90 (232) 388 73 74

Fax: +90 (232) 388 40 43

www.koroglugroup.com

e-mail: medical@koroglugroup.com



Labex Engineering Ltd
40 Lutfiye st., Sofia 1618, Bulgaria
Tel: +3592 818 03 81; Fax: +3592 818 03 86



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