Laboquick MENOPAUSE TEST

Laboquick Menopause Test User's Manual

Intended Use:
Laboquick Menopause Test is an immunochromatographic based one step quick test that aimed at qualitative detection of human follicle-stimulating hormone (FSH) in urine. The test is for in-vitro usage. For Self Testing Home Use.
Product Code: LBMN.02

Summary:
Follicle-stimulating hormone (FSH) is associated with an indicator of low estrogen and menopause. Usually when a woman enters Menopause period, follicle-stimulating hormone (FSH) rises remarkably in body. Generally FSH rises 10 times upper from the normal values and it comes to 110 mIU/ml. This value can rise up to 500 mIU/ml. After menopause FSH level can be stable for many years. One Step FSH Urine test detects this hormone in urine.

Test Principle:
The menopause test device consists of a sample window including a sample ped that the urine is dripped on it. Sample ped 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 – FSH 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 FSH in the sensitivity range of the device, anti- FSH 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 FSH 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 FSH. 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.

Package Contents:
Menopause Test, disposable plastic pipette, silica gel bag as humidifier.

Materials which are necessary for the test but did not included in the package.
Sample Collection Container, chronometer.

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.

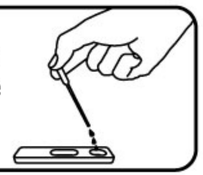
Warnings and Cautions:
1.Read the instructions before use.
2.Do not ever freeze the tests. If the test was stored in a refrigerator, wait the product reaches to the room temperature before use. The test must be carried out in room temperature (between 15 – 30 degrees).
3.Do not use a test after expiry date.
4.Use only human urine as a sample.
5.Observe carefully the number of drops. Only 3-4 drops must be dripped on the test.
6.After removing the testing device from it's 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. Test device must be 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. Results should be read in 5 min. Results that occurred after 10 minutes shouldn't taken into consideration.

Evaluation of the results:

7.

NEGATIVE

The presence of a single line in the "C" in the result window ONLY, indicates a NEGATIVE result.

POSITIVE

The presence of a line in the "C"result Window AND the "T" result window, indicates a POSITIVE result.

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.

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.

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

Test Limitations:
1. Oral contraception pills, skin contraception application, hormone treatment, estrogen treatment or any other hormone intake can affect this test's working and can result to false positive results. Ovulary and pituitary gland tumours can cause false results. This test is good at diagnosing FSH levels at cut off level or above but can give false results at a very low percentage.
2. This tests results cannot be used for fertility or opposite decisions. This test is only for FSH use and cannot be used for pregnancy and ovulation test. Any contraception decision cannot be taken by taking consideration of this test.
3. Test results are not enough to give an exact identification. The final diagnosis should be completed by a physician.

References:

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HAM.LMKK.01
Rev.001
Publishing Date: 13.05.2009

Manufacturer:
Köroğlu Tıbbi Malz. 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

EC REP
Labex Engeneering Ltd
46 Ljubljana str., Sofia 1618, Bulgaria
Tel: +3592 818 03 81; Fax: +3592 818 03 86

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