

# Laboquick PREGNANCY TEST

## Laboquick Pregnancy Test User's Manual

### Intended Use

LaboquickPregnancy Test is an immunchromatographic based one step quick test that is aimed at qualitative detection of human chorionic gonadotropin hormone (hCG) in urine/serum. The test is for in-vitro professional usage only.

Product Code: LBHG.01

### Summary

Human chorionic gonadotropin (hCG) is secreted by the placenta after insemination. hCG can be defected in human urine (and also in blood or serum) at least 5-15 days after the pregnancy has started. The hCG level in the urine/serum after the first missed period is generally around 100mIU/ml and in the first three months the hCG levels rise and reach100,000-200,000 mIU/ml. Easy detection of hCG in urine and serum right after insemination and rapidly rising levels in the early stages of pregnancy make this hormone a reliable and good detection material for early diagnosis of pregnancy. The aim of this test is to detect early beta hCG development that is above 20mIU/ml.

### Test Principle

The pregnancy test kit consists of a sample window including a sample cavity on which the urine sample is placed. The pad in the cavity is held by a permeable membrane. The membrane consists of three antibody areas. The mobile area includes monoclonal antibodies and color sensitive colloidal gold particles. The stable area that forms the test line includes anti-hCG antibodies on the membrane. The third area that forms the control line includes an anti-mouse immunoglobulin. If the sample includes enough hCG in the sensitivity range of the device, anti-hCG forms a compound with colloidal gold conjugate and moves towards to the test area that is indicated by the letter "T". Once the compound is bound, a line is formed in the area "T". The absence or presence of this line shows a negative or a pozitive test result. The colloidal gold particles that are not bound in the test area move towards to the control line to area to form control line regardless to the presence of hCG. The line that forms in this area acts as a control device by confirming that there is enough sample in the device and that the sample followed the correct flow course.

### Package Contents

hCG Pregnancy cassette test, disposable plastic dropper, User's Manual, siliga gel bag as humidifier.

### Materials which are necessary for the test but 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 frozen. The test kit will provide valid results under these conditions provided that it is used prior to the expiry date and the package has not been opened.

### Warnings and Cautions

1. Read the instructions before use.
2. Do not freeze the tests. However if the test was stored in a refrigerator, wait until the test kit reaches room temperature before use (+4° to +30°C).
3. Do not use after the expiry date has passed.
4. Use only human urine as a sample.
5. Only 2-3 drops must be placed on the test.
6. Use immediately, after removing the test kit from it's packaging.
7. If the packaging has been tampered with, the device must not be used.
8. To prevent mixing between samples, use a different disposable sample dropper for each test.
9. Carry out the test in a smoke and contaminant free environment.
10. The device is just for outer body diagnosis.
11. Dispose the test after single use.

## Test Usage Procedure

**1** Collect the urine in a clean, dry and contaminant free plastic or glass container.

**2** Remove the test from the packaging just before starting the test.  
Place the test on a flat surface

**3** Use the plastic dropper to collect the urine from the container.

**4** Place 2-3 drops of urine in the sample cavity on the test kit

### Evaluation of the results

Results appear within 5 minutes of placing the urine sample on the test kit. Discard any results that appear after 10 minutes of testing.



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



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



If there are no lines in the result window after 5 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, dry and contaminant free plastic or glass container.
2. The urine sample can be taken at any time of a day. However the first urine in the morning provides the highest level of hCG concentrations.
3. Any sample collected and stored at room temperature sholud be used within 24 hours.

\* Due to low hCG levels in the early stages of the pregnancy, the result lines may be lighter. The presence of a light line in the area denoted by "T" must be treated as a positive result.

Cut-off Value. The test can detect a min, 20mIU/ml hCG in urine.

Sensitivity: 100%  
Specificity: 99,9%

## References

1. Batzer, F.R. Fertility and Sterility Vol. 34, 1, 1980
2. Catt, K.J., Dufan, M.L. and Vaitukaitis, J.L.J. Clin. Endocrinol Metab., Vol.40,537,1975
3. Baunstein, G.D. Rasor J Adler D Danzer H wade M.E. Am J Obstet Gynecol Vol 126, 678, 1976
4. Lenton,E.A Neal L.M.Sulaiman R Fertility and Sterility Vol. 37,773,1982
5. Dawood MY, Saeba BB, & Landesman R. Ob. Gyn. Vol.126,678,1976
6. Engvall E. Methods in Enzymology, Vol. 70, pp 419-439, 1980.
7. Lenton EA, Neal LM, Sulaiman R. Fertility & Sterility, Vol. 37,773,1982
8. Uotila M,Ruoslahti E,Engvall E.J. Immunol. Methods,Vol. 42,11,1981.
9. Baunstein GD, et al. Ann. Inter. Med. Vol. 78, pp 39-45, 1973.
10. Mahantesh, A.K. Urine pregnancy test and intrauterine inseminations. The Lancet. 363,362 (2004)

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