HCG CARD

METHOD – LATERAL FLOW IMMUNOASSAY
PRODUCT CODE – RC10

ANAMOL
THE ORIGINAL MAKERS

INSTRUCTIONS FOR USE

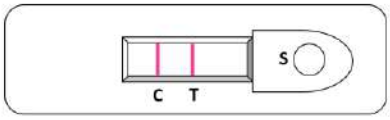
INTENDED USE: Test for detection of HCG in urine samples to aid early detection of pregnancy.

CLINICAL SIGNIFICANCE

Human chorionic gonadotropin (HCG) is a glycoprotein hormone produced by the developing placenta shortly after fertilization. In normal pregnancy, HCG can be detected in both urine and serum as early as 7 to 10 days after conception. HCG levels continue to rise very rapidly, frequently exceeding 100 mIU/mL by the first missed Menstrual period, and peaking in the 100,000-200,000 mIU/mL range about 10-12 weeks into pregnancy. The appearance of HCG in both urine and serum soon after conception, and its subsequent rapid rise in concentration during early gestational growth, make it an excellent marker for the early detection of pregnancy. The HCG Pregnancy Test Strip (Urine) is a rapid test that qualitatively detects the presence of hCG in urine specimen at the sensitivity of 25 mIU/mL. The test utilizes a combination of monoclonal and polyclonal antibodies to selectively detect elevated levels of HCG in urine.

PRINCIPLE

The HCG Pregnancy Test Card (Urine) is a rapid chromatographic immunoassay for the qualitative detection of human chorionic gonadotropin (HCG) in urine to aid in the early detection of pregnancy.



The test utilizes a combination of antibodies including a monoclonal HCG antibody to selectively detect elevated levels of HCG. The assay is conducted by applying urine sample in the sample well and observing the formation of coloured lines. The specimen migrates via capillary action along the membrane to react with the coloured conjugate. Positive specimens react with the specific antibody-hCG coloured conjugate to form a coloured line at the test line region of the membrane. Absence of this coloured line suggests a negative result. To serve as a procedural control, a coloured line will always appear at the control line region if the test has been performed properly.

KIT COMPONENTS

Test Device, Sample Dropper and Instructions for use.

PRECAUTIONS

1. Handle all specimens as if they contain infectious agents.
2. Wear protective disposable gloves when specimens are being tested.
3. Dispose all the samples and kit properly as per the instruction after test in accordance in GLP
4. Read the instructions carefully before performing the test.

STORAGE & STABILITY

The kit can be stored at room temperature or refrigerated (2-30 °C). The test cassette is stable through the expiration date printed on the sealed pouch. The test cassette must remain in the sealed pouch until use. DO NOT FREEZE. Do not use beyond the expiration date.

SPECIMEN COLLECTION AND PREPARATION

The urine specimen must be collected in a clean, dry plastic or glass container. The first morning urine is preferred since it generally contains the highest concentration of HCG. However, urine collected at any time of day may be used. Urine samples exhibiting visible precipitates should be centrifuged, or allowed to settle to obtain clear supernatant for testing. Urine specimens may be stored at 2-8 °C for up to 48 hours prior to assay. Urine containing excessive bacterial contamination should not be used as this may cause spurious results.

TEST PROCEDURE

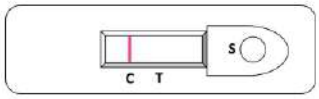
Allow test cassette, specimen, and/or controls to equilibrate to room temperature (15-30 °C) prior to testing.

1. Place the test device on a clean and level surface. Add 2 drops (40 µl) of urine sample to the sample well "S" of the test device.
2. Immediately start the timer.
3. Wait for the coloured line(s) to appear. The test line should be read at 3-5 minutes. It is important that the background is clear before the result is read.

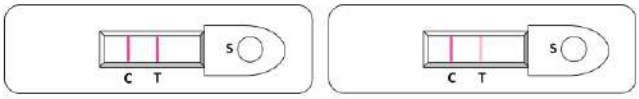
Note: Do not interpret results after 10 minutes.

INTERPRETATION OF THE RESULTS

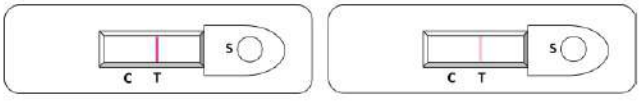
NEGATIVE RESULT:
Only one pink-purple coloured line appears at the control zone 'C' (Control line) the test result is negative



POSITIVE RESULT:
Two distinct purple lines appear. One line should be in the control region (C) and another line should be in the test region (T).



INVALID TEST:
Control line fails to appear. In sufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test with a new test device. If the problem persists, discontinue using the test kit immediately and contact your local distributors.



SPECIFICITY

The specificity of the HCG Pregnancy Test Card was determined from cross-reactivity studies with known amounts of Luteinizing Hormone (hLH), Follicle Stimulating Hormone (hFSH), and Thyroid Stimulating Hormone (hTSH). Negative results were obtained from all IU/mlµtests conducted with 500 mIU/ml hLH, 1000 mIU/ml hFSH and 1000 hTSH.

SENSITIVITY

The analytical sensitivity of the hCG Pregnancy Test Card is 25 IU/ml. The sensitivity was established by repetitive testing of samples containing 25 IU/ml hCG during a period of several weeks.

LIMITATION OF PROCEDURE

Very dilute urine specimens as indicated by low specific gravity may not contain representative levels of hCG. If pregnancy is still suspected, a first morning urine sample should be obtained 48-72 hours later and tested. Very low levels of HCG (less than 50m IU/ml) are present in urine shortly after implantation. However, because a significant number of first trimester pregnancies terminate for natural reasons, a test result that is weakly positive should be interpreted in conjunction with other clinical and laboratory data. A number of conditions other than pregnancy, including trophoblastic disease and certain non-trophoblastic neoplasms including testicular tumors, prostate cancer, breast cancer, and lung cancer, cause elevated levels of hCG . Therefore, the presence of hCG in urine as determined by using hCG Pregnancy Test Strip should not be used to diagnose pregnancy unless these conditions have been ruled out. As with all diagnostic tests, a confirmed pregnancy diagnosis should only be made by a physician after all clinical and laboratory findings have been evaluated.

EXPECTED VALUES

Urine and serum HCG concentration of pregnant women rise very rapidly after implantation, reaching a peak concentration in excess of 100 IU/ml about 2-3 months after the last menstrual period.

The HCG Pregnancy Test Strip has a sensitivity of 25 mIU/ml and is capable of detecting pregnancy as early as 1 day after the first missed menses. Reportedly, a level of 25 mIU/ml or more, is present 7-10 days after conception or 4-5 days prior to the first missed menses.

Test results which appear as a very light line in the test region are not definitive for the diagnosis of pregnancy. It is strongly recommended that an additional urine specimen be obtained after 48-72 hours and tested again.

Negative test results in patients suspected to be pregnant should be re-tested with the first morning specimen obtained 48-72 hours later.

BIBLIOGRAPHY

1. Balzer FR. *Fertility and Sterility* 1980; 34:l
2. Catt KJ, ML Dufan, JL Vaitukaitis. *J. Clin. Endocrinol. Metab.* 1975; 40:537
3. Baunstein GD, J Rasor, D Adler, H Danzer, ME Wade. *Am. J. Obstet. Gynecol.* 1976; 126:678
4. Lenton EA, LM Neal, R Sulaiman. *Fertility and Sterility* 1982; 37:773
5. Engvall E. *Methods in Enzymology* 1980; 70:419
6. Uotila M, E Ruoslahti, EJ Engvall. *E. J. Immunol. Methods* 1981; 42:11
7. Steier JA, P Bergsjo, OL Myking. *Am. J. Obstet. Gynecol.* 1984; 64:391
8. Dawood MY, BB Saxena, R Landesman. *Am. J. Obstet. Gynecol.* 1977; 50:172
9. Braunstein GD, JL Vaitukaitis, PP Carbone. *Ann,Inter. Med.* 1973; 78:39

SYMBOLS:


Read Instruction for use

In Vitro Diagnostic Use Only


Manufactured by


Expiry Date


Storage Temperature

ANAMOL LABORATORIES PVT. LTD.
61, Genesis Industrial Township, Kolgaon,
Palghar – 401 404. India.
Customer Care: +91-9823388695.

admin@anamollabs.com
exports@anamollabs.com
www.anamollabs.com

ISO 9001 : 2015
ISO 13485 : 2003
GMP
CE