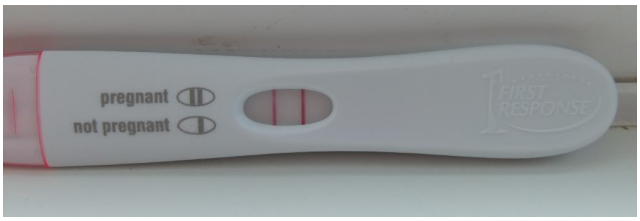
For M Sc Zoology 4 Sem (Endo Spl) By : Prof Lata Bhattacharya

Diagnosis of Pregnancy by Urine hCG Level Test

Introduction:

A human chorionic gonadotropin (hCG) urine test is a pregnancy test. A pregnant woman's placenta produces hCG, also called the pregnancy hormone. If you're pregnant, the test can usually detect this hormone in your urine about 10 days after your first missed period. This is when the fertilized egg attaches to the uterine wall.

During the first 8 to 10 weeks of pregnancy, hCG levels normally increase very rapidly. These levels reach their peak at about the 10th week of pregnancy, and then they gradually decline until delivery.



This type of urine test is commonly sold in kits that you can use at home. It's often is referred to as a home pregnancy test.

There are two types of pregnancy tests; one uses a urine sample, the other a sample of blood. Both pregnancy tests detect the presence of a hormone called human chorionic gonadotropin (hCG). This hormone is produced by the placenta shortly after the embryo attaches to the uterine lining and builds up rapidly in your body in the first few days of pregnancy.

It is this rapid shift in hormones that trigger most of your pregnancy symptoms.

Urine Tests

Urine tests can be performed in two different ways and these can be performed at home or in a clinic. One way involves collecting your urine in a cup and dipping a stick into the urine or putting urine into a special container with an eyedropper. Another option involves placing a stick into your urine stream and catching your urine in midstream.

Tests vary in how long you have to wait to get a result. You will be looking for a change in color, a line, or a symbol (like a plus or minus). The newer digital pregnancy test offered by Clearblue Easy makes reading your results simple: the window will either show the words "not pregnant" or "pregnant".

When can I take a urine test?

Most doctors recommend that you wait until the first day of your missed period before taking a urine pregnancy test. This is usually about **two weeks after conception**. However, some tests are more sensitive than others and can be taken earlier.

Accuracy:

Urine tests or home pregnancy tests are around **97% accurate** when done correctly. Home pregnancy tests are great to use because they can be done at home, they are usually low in cost , private, they give a fast result, and are easy to use.

However, if done incorrectly or taken too early, the result can be inaccurate. If you get a negative result and still have symptoms of pregnancy (missed period, nausea, breast tenderness, and fatigue), wait a week and take another test or contact your doctor so you can have a blood test done.

What are the uses of the hCG urine test?

The hCG urine test confirms pregnancy about one to two weeks after your missed period. This is a qualitative test, which means that it will tell you whether or not it detects the hCG hormone in urine. It's not intended to reveal specific levels of the hormone. The presence of hCG in urine is considered a positive sign of pregnancy.

Are there risks involved with this test?

The only risks associated with an hCG urine test involve getting a false-positive or false-negative result.

PREGNANCY TESTING URINE AND SERUM

Prinicipal

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 the 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 Consult Diagnostics hCG Combo Test is a rapid chromatographic immunoassay for the qualitative detection of human chorionic gonadotropin (hCG) in urine or serum to aid in the early detection of pregnancy. The test utilizes a combination of antibodies including mouse monoclonal anti-hCG antibodies and goat polyclonal anti-hCG antibodies to selectively detect elevated levels of hCG. The assay is conducted by adding urine or serum to the specimen well of the test cassette and observing the formation of colored lines. The specimen migrates via capillary action along the membrane to react with the colored conjugate.

Positive specimens react with the specific colored antibody conjugates and form a colored line at the test line region of the membrane. Absence of this colored line suggests a negative result. To serve as a procedural control, a colored line will always appear at the control line region if the test has been performed properly.

The test qualitatively detects the presence of hCG in urine specimen at the sensitivity of 20 mIU/mL for urine and 10 mIU/ml for serum.

REAGENTS

The test cassette contains mouse anti-beta hCG antibody conjugated to colloidal gold and goat anti-alpha hCG antibody coated on the membrane.

MATERIALS

Materials Provided

• Test cassettes

• Disposable pipettes

• Instructional insert Materials

Required But Not Provided

• Specimen collection container

• Timer

SPECIMEN COLLECTION AND PREPARATION

A urine specimen must be collected in a clean and dry container. A first morning urine specimen is preferred since it generally contains the highest concentration of hCG; however, urine specimens collected at any time of the day may be used. Urine specimens exhibiting visible precipitates should be centrifuged, filtered, or allowed to settle to obtain a clear specimen for testing.

Blood should be collected aseptically into a clean tube without anticoagulants. Seperate the serum from the blood as soon as possible to avoid hemolysis. Use clear non-hemolyzed specimens when possible.

Specimen Storage

Serum or urine specimens may be stored at 36-46°F (2-8°C) for up to 48 hours prior to testing. For prolonged storage, specimens may be frozen and stored below -4°F (-20°C). Frozen specimens should be thawed and mixed before testing.

Procedure:

DIRECTIONS FOR USE:

Allow the test cassette, specimen and/or controls to equilibrate to room temperature (59-86°F; 15-30°C) prior to testing.

1. Remove the test cassette from the sealed pouch and use it as soon as possible.

2. Place the test cassette on a clean and level surface. Hold the pipette vertically and transfer 3 full drops of urine or serum (approx. 100 µL) to the specimen well of the test cassette, and then start the timer. Avoid trapping air bubbles in the specimen well.

3. Wait for the red line(s) to appear. Read the result at 3-4 minutes for urine or 5-6 minutes for serum. Do not interpret results after the appropriate read time. It is important that the background is clear before the result is read.

Key Points:

INTERPRETATION OF RESULTS

POSITIVE*: Two distinct red lines appear. One line should be in the control region (C) and another line should be in the test region (T). NOTE: A sample hCG concentration below the cut-off level of this test might result in a weak line appearing in the test region (T) after an extended period of time. A line in the test region (T) seen after the read time could be indicative of a low hCG level in the sample. If such results are seen, it is recommended that the test be repeated with a new sample in 48-72 hours or that an alternate confirmation method is used.

NEGATIVE: One red line appears in the control region (C). No apparent red or pink line appears in the test region (T).

INVALID: Control line fails to appear. Insufficient 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 cassette. If the problem persists, discontinue using the test kit immediately and contact Technical Service at 1-877-441-7440, Option 2.

*NOTE: The intensity of the red color in the test line region (T) will vary depending on the concentration of hCG present in the specimen. However, neither the quantitative value nor the rate of increase in hCG can be determined by this qualitative test.

QUALITY CONTROL

Internal procedural controls are included in the test. A red line appearing in the control region (C) is the internal procedural control. It confirms sufficient specimen volume and correct procedural technique. A clear background is an internal negative background control. If the test is working properly, the background in the result area should be white to light pink and not interfere with the ability to read the test result.

Exteranal controls hCG urine: Quantimetrix Dropper Plus Positive and Negative control are run every thirty days, with each new lot, each new shipment and each new operator. Results are entered in the LIS and the date is recorded on the "Quick Check..." chart on the cupboard door.

External Contros hCG Serum: Stanbio hCG Trilevel Serum Controls, two positive levels and one negative level are run with each patient sample. Results are entered in LIS.

LIMITATIONS

1. Very dilute urine specimens, as indicated by a low specific gravity, may not contain representative levels of hCG. If pregnancy is still suspected, a first morning urine specimen should be collected 48 hours later and tested.

2. False negative results may occur when the levels of hCG are below the sensitivity level of the test. When pregnancy is still suspected, a first morning urine or serum specimen should be collected 48 hours later and tested.

3. Very low levels of hCG (less than 50 mIU/mL) are present in urine specimen 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 confirmed by retesting with a first morning serum or urine specimen collected 48 hours later.

4. This test reliably detects intact hCG up to 500,000 mIU/mL. It does not reliably detect hCG degradation products, including free-beta hCG and beta core fragments. Quantitative assays used to detect hCG may detect hCG degradation products and therefore may disagree with the results of this rapid test.

5. 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 serum or urine specimens should not be used to diagnose pregnancy unless these conditions have been ruled out.

6. This test provides a presumptive diagnosis for pregnancy. A confirmed pregnancy diagnosis should only be made by a physician after all clinical and laboratory findings have been evaluated.

Sensitivity and Specificity

The Consult Diagnostics hCG Combo Test – Cassette detects hCG at a concentration of 20 mIU/mL or greater in urine and 10 mIU/ml or great in serum. The test has been standardized to the W.H.O. Third International Standard. The addition of LH (300 mIU/mL), FSH (1,000 mIU/mL), and TSH (1,000 μIU/mL) to negative (0 mIU/mL hCG) and positive (25 mIU/mL hCG) specimens showed no cross-reactivit.