



PREGNY-SCANTM

One Step hCG STRIP TEST

READ THE PACK INSERT CAREFULLY BEFORE PERFORMING THE TEST

Catalogue No. : PSD

Pregny-Scan Strip is an advanced, rapid, one-step pregnancy test for the determination of the pregnancy hormone hCG (human Chorionic Gonadotropin) in urine. The high sensitivity of the Pregny-Scan Strip means that the pregnancy can be detected as early as 7 days post-impianfEtion

Introduction : human Chorionic Gonadotropin (hCG) is a glycoprotein hormone produced by the placenta. In a normal pregnancy, hCG appears in serum and in urine soon after conception. Concentration of the hormone increases rapidly and therefore, it serves as an indicator of pregnancy. The level of urinary hCG is about 100mIU/ml at the time of first missed menstrual period. The highest values (~200,000 mIU/ml) can be demonstrated later in the first trimester of pregnancy.

Test Principle : The hCG test device consists an absorbent pad where it is dipped into urine. The absorbent pad is held in contact with the porous membrane material. The membrane has three zones of antibody, the first is mobile while the other two are immobile. The mobile zone consists at coloured colloidal gold particles sensitized with monoclonal antibody to anti-hCG antibody immobile on the membrane (test line). The third zone (control line) consists of an anti-mouse immunoglobulin antibody, which is also immobile. If the urine contains hCG, it will form a complex with the anti-hCG colloidal gold conjugate and then move on to be trapped by the test line, causing the formation of a red line. The unbound colloidal gold particles move on to be successfully trapped by the control line, giving a red line as well.

Storage and Stability : The kits can be stored at room temperature between 2-30^o C. They are stable until the expiry date mentioned on the pouch when stored under the above conditions.

Pack Size : Available in packs of 20's, 50's and 100's

Contents of the Kit: One testing device, and Silica Gel as a dehydrant.

Specimen Collection and Preparation : Urine must be collected in a clean, dry plastic or glass container without any preservative. Specimens collected at any time of the day may be used although the first morning urine is known to have higher levels of hCG. Urine specimens not tested within 24 hours must be frozen (-20^o C) and can thus be stored for another 48 hours prior to testing. Samples should be fully thawed to room temperature and mixed well before testing.

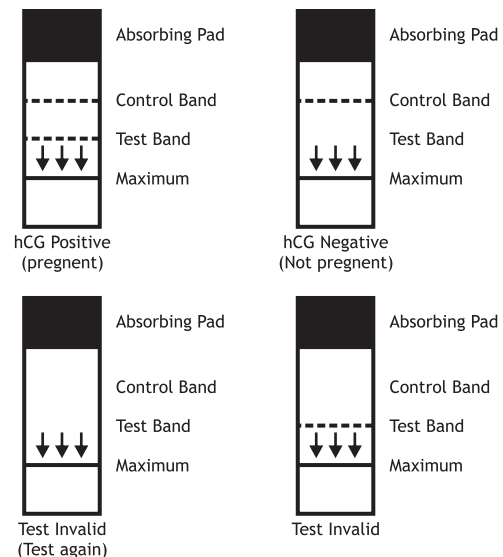
Precautions :

1. Read this Pack Insert carefully.
2. DO NOT FREEZE THE KITS.
3. Do not use after the expiration date.
4. Use only urine specimens.
5. Do not dip the strip above the Max line.
6. The Pregny-Scan Test Pack if refrigerated, should be brought down to room temperature before testing. Assay should be conducted at room temperature (15-30^oC)
7. Use the kit soon after removing from the aluminum pouch.
8. Do not use the test device, if the pouch seal is broken.
9. Frozen specimens should be brought to room temperature before testing.
10. For invitro diagnostic use only.

Quality Control : Each Dipstick has its own built in quality control indicator. If after performing the test no line is visible on the Dipstick or questionable results are obtained, please repeat the test using a new Pregny-Scan One Step Pregnancy Dipstick.

Assay Procedure :

1. Remove the Test Strip from the pouch.
2. Hold the absorbing pad and dip the strip in the urine upto the Max-Line with the arrow end pointing down for 5 to 10 seconds
3. Read the results after 5 minutes. Do not read any result beyond 10 minutes.



Sensitivity : The Pregny-Scan One Step Pregnancy Dipstick test will yield a positive result as early as 7-10 days post conception (20mIU/ml).

Specificity: Beta - hCG Specific

Limitation : In addition to Pregnancy, hCG has been found in patients with both gestational and nongestational trophoblastic disease. hCG of trophoblastic neoplasma is similar to that found in pregnancy. These conditions, which include choriocarcinoma and hydatidiform mole, should be ruled out before diagnosis of pregnancy is reached.

If negative or questionable results are obtained, and pregnancy is suspected, the test should be repeated with a fresh urine specimen at least 48 hours after initial testing.



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