

PREGNY - SCANTM

hCG Dipstick Test

A Rapid One Step Visual test for the qualitative detection of human Chorionic Gonadotropin in urine

For Professional Use -



CE

READ THE PACK INSERT CAREFULLY BEFORE PERFORMING THE TEST

Catalogue No. : PSD

Intended Use :

PREGNY-SCAN hCG Dipstick Test is an immunochromatographic based assay for the detection of human chorionic Gonadotropin in urine.

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 as 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 of colored colloidal gold particles sensitized with monoclonal antibody to anti-hCG antibody immobilized on the membrane (Test line). The third zone (Control line) consists of 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°C - 30°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.

Material Required but not provided : Urine Container

Warnings & Precautions :

In order to obtain reproducible results, the following rules must be observed:

- a). Read this Pack Insert carefully.
- b). DO NOT FREEZE THE KITS. If refrigerated the kits should be brought to room temperature before testing. Assay should be conducted between 15-30°C.
- c). If the sample is turbid or viscous centrifuge the sample at 5,000rpm for 15 minutes.
- d). Do not use the kits beyond their expiry date.
- e). Use only urine samples.
- f). Do not dip observe the prescribed number of drops to be added, 2 - 3 DROPS ONLY.
- g). Use the test device soon after it is removed from the pouch.
- h). Do not use the test device, if the pouch seal is broken.
- i). Avoid any contamination among samples; for this purpose, disposable tips should be used for each sample and reagent.
- j). Do not smoke, eat drink or apply cosmetics during the assay.
- k). For In vitro Diagnostic Use only.
- l). **Hook's Effect :** In exceptional cases, during the first 2-3 months of Pregnancy, the hCG level may reach above 200,000 mIU/ml. When the level reaches this level, the test based on immuno-chromat-ographic method may show weak test line, due to "Hook's Effect". In such cases it is advisable to test the urine after diluting 10 times to get a dark test line.
- m). For Single Use only.
- n). All Specimens Should be considered potentially hazardous and handled in the same manner as an infectious agent.
- o). The used test should be discarded according to local regulations.

Specimen : Fresh Urine

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

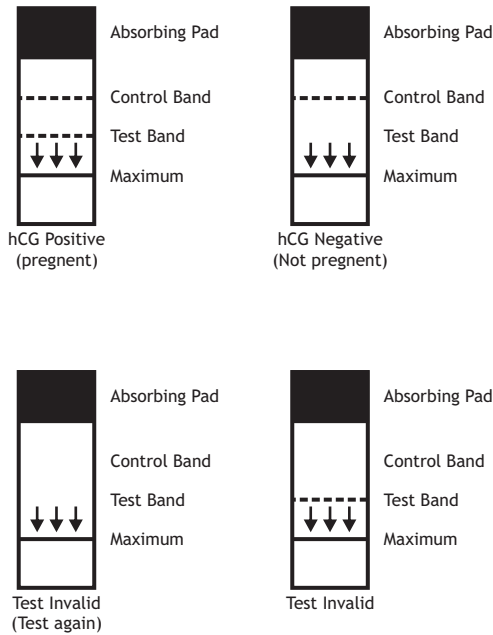
higher levels of hCG. Urine specimens if not tested within 24 hours must be frozen (-20°C) and can thus be stored for another 48 hours prior testing. Samples should be fully thawed to room temperature and mixed well before testing.

Assay Procedure :

- Collect urine in a clean container.
- Bring the kit and samples to Room Temperature.
- Remove the device from the pouch just prior to testing.
- Hold the absorbing pad and dip the strip in the urine upto the MAX-line with the arrow end pointing down for 5-10 seconds.
- Read the results after 5 minutes. **DO NOT INTERPRET BEYOND 10 MINUTES.**
- Any line appearing after 10 minutes would be of no diagnostic value.

Interpretation of Test Result :

Negative : The presence of only one Band at "C" within the result window indicates a Negative Result.



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.

Reference

- Batzer F.R. Fertility and Sterility. Vol. 34. 1. 1980
- Catt, K.J., Dufan. M.L. and Valtukaltis, J.L.J. Clin. Endocrinol. Metab., Vol.40. 537. 1975
- Baunstein. G.D., Rasor. J. Adler. D., Danzer. H., Wade. M.E. Am.J. Obslet. Gynecol., Vol. 126, 678, 1976
- Lenton. E.A., Neal. L.M. Sulaiman. R Fertility and Sterility. Vol. 37. 773. 1982
- Batzer, F.R. Fertility and Sterility. Vol. 34. 1. 1980

EN 980:2008 (E) MEDICAL DEVICES SYMBOL

	Temperature Limitation		Date of Manufacture
	Batch Code		Company name & address
	Use by		Company name
	In vitro Diagnostic Device		Authorised Representative in European Community
	Refer Operating Instructions		Do Not Reuse
	Sufficient for		KEEP AWAY FROM SUNLIGHT
	KEEP DRY		NON-STERILE
	NEGATIVE CONTROL		POSITIVE CONTROL

M/S PDB Consulting
 Bruno Rosen, Flehenburg
 48, 42489 Walfrath, Germany
 P : + 49 - 2058 - 8989881
 Fax : + 49 - 2058 - 8989882



Mfg. in India by :

BHAT BIO-TECH INDIA (P) LTD.

No. 11-A, 4th Cross, Veerasandra Indl. Area,
 Electronic City, Bangalore - 560 100
 Phone : 080-4351 4000 (30 Lines)
 Fax : 080-4351 4001 www.bhatbiotech.com