hCG Card Test

PREGNY-SCAN®

For Professional Use

IVD

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

Read the Pack Insert before use provided along with the kit

REF PSC

INTENDED USE : hCG Card Test PREGNY-SCAN® is an immunochromatographic based assay for the detection of human chorionic Gonadotropin in urine.

INTRODUCTION : human Chorionic Gonadotropin (hCG) is a glycoprotein hormoneproduced 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 PRINCIPLES : The hCG test device consists of a sample window containing sample pad where the urine is to be added. The sample 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 coloured colloidal gold particles sensitized with monoclonal antibody. The second zone consists of anti hCG immobilised on the membrane (test line). The third zone (control line) consists of an anti-mouse immunoglobulin. 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 to 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 25test, 50test and 100test.

CONTENTS OF THE KIT One testing device, One 2ml dropper andSilica 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 to 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). Carefully 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 immunochromatographic 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 :

1. Bring the pouch to room temperature.
2. Remove the device from the pouch just prior to testing.
3. Place the device on a flat surface.
4. Add 2-3 drops of urine on sample window.
5. Read the results after 5 minutes.

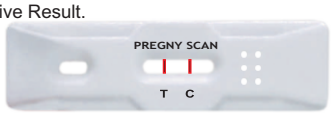
DO NOT INTERPRET BEYOND 10 MINUTES.

g). Any line appearing after 10 minutes would be of no diagnostic value.

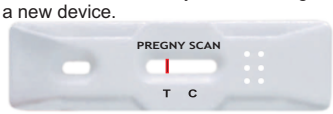
INTERPRETATION OF TEST RESULT :

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

Positive : The presence of Two Bands at "C" and "T" within the result Window, indicates the Positive Result.



Invalid : If no lines appear or only Test Line appears within the result window after performing the test, the result is considered invalid. The directions may not have been followed correctly or the silica gel might have turned white. Repeat the test with a new device.



Sensitivity :
The Pregny-Scan will yield positive result with hCG concentration as low as 20 mIU/ml or as early as 7 days post-implantation.

Specificity : Beta - hCG Specific

LIMITATION :

In addition to Pregnancy, hCG has been found in patients with both gestational and nongestational trophoblastic diseases.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 a t least 48 hours after initial testing.

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,

NOTE:: Even after the best effort is made to supply the product as per the sample submitted but due to continuous R & D, the company reserves the right to improve/change any specifications/components without prior information/notice to the buyer

LIMITED EXPRESSED WARRANTY OF MANUFACTURER

The manufacturer limits the warranty to this test kit, as much as that the test kit will function as an in vitro diagnostic assay within the Nature of Sample, Procedure limitations and specifications as described in the product instruction manual, when used strictly in accordance with the instructions contained. The manufacturer disclaims any warranty expressed or implied including such expressed or implied warranty with respect to merchantability, fitness for use or implied utility for any purpose. The manufacturer's liability is limited to either replacement of the product or refund of the purchase price of the product and in no case liable to claim of any kind for an amount greater than the purchase price of the goods in respect of which damages are likely to be claimed. The manufacturer shall not be liable to the purchaser or third parties for any injury, damage or economic loss, howsoever caused by the product in the use or in the application there of.

BS ISO-15223-1:2012(E) MEDICAL DEVICES SYMBOL					
2°C 30°C	Temperature Limitation	2001-06	Date of Manufacture	IVD	In vitro Diagnostic Device
LOT	Batch Code		Company name & address		Consult Instructions For Use
	Use by	Company	Company Name	EC REP	Authorised Representative in European Community
	Do Not Reuse	Σ	Sufficient for		KEEP AWAY FROM SUNLIGHT
	KEEP DRY	NON STERILE	NON-STERILE	CONTROL -	NEGATIVE CONTROL
CONTROL +	POSITIVE CONTROL				

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