

# PREGNY-SCAN<sup>TM</sup>

## Midstream hCG Test

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

For Professional Use



**READ THE PACK INSERT CAREFULLY BEFORE PERFORMING THE TEST**

### GENERAL DESCRIPTION OF THE PRODUCT

**INTENDED USE:** The one step Pregny scan hCG midstream test is an immune chromatography based assay for the qualitative detection of human chorionic gonadotropin (hCG) in human 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. The concentration of the hCG 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 levels of hCG ( 200,000 mIU/ml) can be demonstrated later in the first trimester of pregnancy.

**PRINCIPLE:** The Pregnyscan Midstream hCG Test is a rapid, One step lateral flow immunoassay in midstream format for the qualitative detection of human chorionic gonadotropin (hCG) in urine to aid in the 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 urinating on the Absorbent Tip or immersing the Absorbent Tip in urine, and obtaining the result from the colored lines

**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 single test.

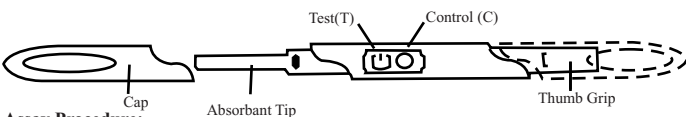
**CONTENTS OF THE KIT :** Individual pack contains one midstream testing device and one silicagel as dehydrant.

#### Warnings & Precautions:

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

- Read this pack insert carefully.
- **DO NOT FREEZE THE KIT.** If refrigerated the kit should be brought to room temperature before testing Assay should be conducted between 15-30° C
- If the sample is turbid or viscous centrifuge the sample at 5,000rpm for 15 minutes.
- Do not use the kits beyond their expiry date.
- Use only urine samples.
- Use the test device soon after it is removed from the pouch.
- Do not use the test device if the pouch seal is broken.
- Avoid any contamination among samples.
- Do not smoke, eat drink or apply cosmetics during the assay.
- For In vitro Diagnostic use only.
- 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-chromatographic 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.
- For Single Use only
- All specimens should be considered potentially hazardous and handled in the same manner as an infectious agent.
- The use test should be discarded according to local regulations.

**Specimen :** Fresh Urine



#### Assay Procedure:

1. Remove the midstream test from the foil pouch and familiarize yourself with the product.
2. Remove the Cap and place it over the Thumb Grip.
3. Hold the midstream test by the capped Thumb Grip with the exposed Absorbent Tip pointing downward directly into your urine stream for at least 10 seconds until it is thoroughly wet.

**Note:** Do not urinate on the Test and Control windows. If you prefer, you can urinate into a clean and dry container, then dip only the Absorbent Tip of the midstream test into the urine for at least 10 seconds.

4. After removing the midstream test from your urine, immediately replace the Cap over the Absorbent Tip, lay the midstream test on a flat surface with the test and control windows facing upwards, and then begin timing.
5. As the test begins to work, you may notice a light colored flow moving across the Test and control windows. Read the result at 3 minutes. If no colored line appears, wait one minute longer. Some positive results may be observed in 1 minute or less depending on the concentration of hCG. Do not read the result after 10 minutes.

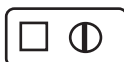
#### INTERPRETATION OF THE RESULT:

**POSITIVE/PREGNANT:** Two distinct coloured lines appear. One line should be in the control window(C)and one should be in the test window(T). One line may be lighter than the other. Both the line do not have to match.



#### NEGATIVE/NOT PREGNANT:

One colored line appears in the control window (C). No line appears in the test window (T).



**INVALID:** The result is invalid if no coloured line appears in the control window (C), even if a line appears in the test window (T). Repeat the test with the new midstream test.



**Sensitivity:** The Pregny-Scan will yield positive result with hCG concentration as low as 25 mIU/ml or as early as 7 days post-implantation.

#### TECHNICAL SPECIFICATION OF THE PRODUCT

1. Sensitivity : The Pregny scan hCG midstream test will detect hCG concentration as low as 25mIU/ml or as early as 7 days post implantation.
2. The pregny scan hCG midstream test is specific to beta hCG. The addition of LH(300mIU/ml), FSH (1,000mIU/ml), and TSH (1,000 µIU/ml) to negative (0 mIU/ml hCG) and positive (25mIU/ml), specimens showed no cross reactivity.
3. The device has a shelf life of 24 months from the date of manufacturing.
4. The device has a control band to validate the result.
5. The device can be stored at room temperature or between 2°and 30° C.
6. Total assay procedure is 10 minutes.
7. No other device is required to read and interpret the result.
8. Available as individual pack.
9. The test device is for single use only. Not for reuse.
10. The device is intended to be used to hCG detect in human urine specimen only. Other body fluids can not be used for testing. The device is for in vitro diagnostic use only

**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 neoplasia 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.

There is the possibility that this test may produce false results Consult your physician before making any medical decisions.

1. Drugs which contain hCG (such as Pregnyl, Profasl, Pregonal and APL) can give a false positive result. Alcohol, Oral contraceptives, painkillers, antibiotics or hormone therapies that do not contain hCG should not effect the test result.
2. A number of medical conditions other than pregnancy, including, ovarian cyst or ectopic pregnancy (pregnancy outside the uterus) can cause elevated levels of hCG, which can result in a false positive result.

#### 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, Vol. 37, 773, 1982.
5. Batzer, F.R. Fertility and Sterility, Vol. 34, 1, 1980

EN 980:2008 (E) MEDICAL DEVICES SYMBOL				
	Temperature Limitation		Date of Manufacture	In vitro Diagnostic Device
	Batch Code		Company name & address	Refer Operating Instructions
	Use by		Company Name	Authorised Representative in European Community
	Do Not Reuse		Sufficient for	KEEP AWAY FROM SUNLIGHT
	KEEP DRY		NON-STERILE	NEGATIVE CONTROL
	POSITIVE CONTROL			

Mfg. In India by :



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