ImmunoScience INDIA

ImmunoQuick

Pregnancy

One Step Pregnancy Test - Dipstick

A test for detection of hCG (human Chorionic Gonadotropin) hormone from human urine

For Self -Testing & *In-Vitro* Diagnostic Use Only **Store at 4°C to 30°C**

OVERVIEW

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 (1-4). hCG levels continue to rise very rapidly, frequently exceeding 100 mIU/mL by the first missed menstrual period (2-4), and peaking in the 100,000-200,000 mIU/mL range about 10-12 weeks into pregnancy. The appearance of hCG in both 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.

INTENDED USE

One step pregnancy test (Dipstick) is a self-testing immunoassay made for the rapid and visual determination of hCG (human Chorionic Gonadotropin) hormone in human urine specimen to aid in the early detection of pregnancy.

PRINCIPLE

The One Step Pregnancy Test (Dipstick) is an immunoassay for the fast detection of hCG in urine. The special membrane is placed in front of a reaction pad which contains colloidal gold particles coated with monoclonal anti-hCG antibodies. If a sample is applied, the colloidal gold particles dissolve in the liquid sample. If the sample contains the hCG hormone (beta-hCG subunit), this is bonded to the monoclonal antibodies marked with colloidal gold particles. The dissolved gold particles are transported through the membrane due to the capillary forces effective in the special membrane. In the area of the Test line (T), the anti-hCG antibodies immobilized there form the complex of hCG and colloidal gold. A colored line is formed depending on the hCG concentration. The surplus colloidal gold particles and mouse IgG colloidal gold particles then move further and bonded in the area of the control-line coated with goat anti mouse IgG antibodies, so that a colored line also becomes visible in this area. This line serves as an internal functional check and must be formed in every test. If no or only very little hCG is present in the sample (< 10 mIU/ml), the hormone-gold particle complex is not formed or it is formed in insufficient amount to generate a visible colored line in the area of the test line.

CONTENTS OF KIT

1. Test Strip: Nitrocellulose membrane assembly pre dispensed with monoclonal anti alpha hCG antibody and Goat Anti Mouse IgG and colloidal gold conjugate with monoclonal anti beta hCG antibody and Mouse IgG at their respective regions.
2. Desiccant Pouch
3. Package Insert

OPTIONAL MATERIAL REQUIRED

1. Stop Watch
2. Sample container
3. Disposable Gloves
4. Test Tube (12x75)mm

PRECAUTIONS/KIT STORAGE AND STABILITY

1. Please read all the information in this package insert before performing the test. Pay particular attention to the position of the Control and Test lines.
2. Do not use after the expiration date printed on the foil pouch.
3. Store in the sealed pouch in a dry place in between temperature 4°C to 30°C. Do not freeze.
4. Do not use if pouch is torn or damaged.
5. Do not open the foil pouch until you are ready to start the test.
6. Keep out of the reach of children.

WARNINGS

1. Do not reuse the test strip.
2. Follow the instruction to get accurate results.
3. Use appropriate personal protective equipment.
4. Dispose off hygienically in domestic waste.
5. Do not touch the membrane.
6. Treat samples and used dipsticks as potentially infectious. Avoid contact with skin.
7. For in vitro diagnostic use. Not to be taken internally.
8. Do not eat the desiccant in the package.
9. Do not mix the specimen sample or interchange the different specimen.
10. The manufacturer and distributor of this product shall not be liable for any loses, liability, claims, costs or damages whether direct or consequential arising out of or related to an incorrect diagnosis, whether positive or negative, in the use of this product.

SPECIMEN COLLECTION

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.

TEST PROCEDURE

1. Allow the Pregnancy Test and urine sample to reach room temperature (20°C to 30°C) before opening the foil pouch.
2. Remove the Pregnancy Test Strip & Desiccant Pouch. Check the color of the Desiccant. It should be blue, if it has turned colorless or pink, discard the test & use another test. Once Opened , the test must be used immediately.
3. With arrows pointing toward the urine specimen, immerse the test strip vertically in the test tube (12 X 75) mm containing urine specimen (Approx. 1ml) (i.e. Pass the test strip in urine up to the MAX mentioned on strip).
4. Start the timer.
5. Read the result at 5 minutes. Do not read the result after 10 minutes.

INTERPRETATION OF RESULTS

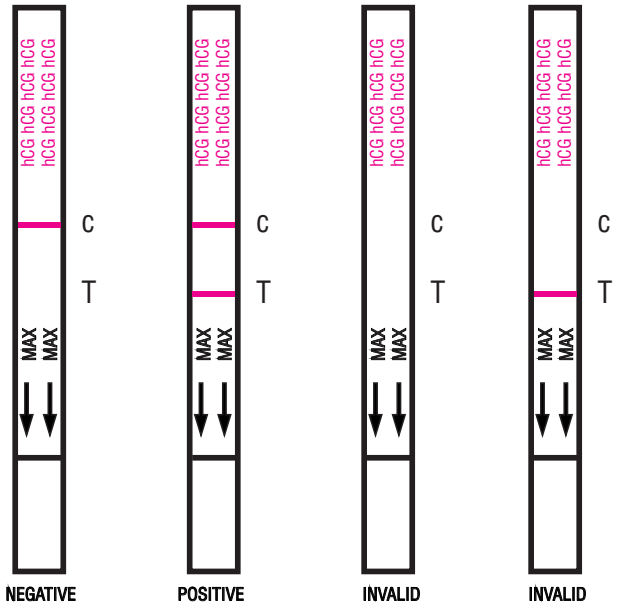
Negative: If colored line appears at the control region 'C' only.

Positive: If colored line appears at the control region 'C' and at the test region 'T'.

Invalid: The test should be considered invalid if,

A) No line appears at control region 'C' and test region 'T'

B) No line appears at control region 'C' and line appear only at test region 'T'



NOTE:

The intensity of the color in the test line (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. Depending on the concentration of hCG in the specimen, positive results may appear as early as 30 seconds. Negative results must be confirmed only at the end of five minutes.

PERFORMANCE CHARACTERISTICS

Internal Evaluation:

In an in-house study, total 250 samples were evaluated for sensitivity and specificity. We found the relative sensitivity was 100 % (i. e. 100/100) and the relative specificity was 100 % (i. e. 150/150).

The results are summarized in the following table:

Sample	Total Number of Samples Tested	One Step Pregnancy Test (Dipstick)		Sensitivity (%)	Specificity (%)
		Positive	Negative		
hCG Positive Urine Samples	100	100	0	100	-
hCG Negative Urine Samples	150	0	150	-	100

External Evaluation:

In an external study, total 250 samples were evaluated for sensitivity and specificity. Relative sensitivity was 100 % (i. e. 50/50) and the relative specificity was 100 % (i. e. 200/200). Positive Predictive Value (PPV) and Negative Predictive Value (NPV) for the test was 100%.

The results are summarized in the following table:

Sample	Total Number of Samples Tested	One Step Pregnancy Test (Dipstick)		Sensitivity (%)	Specificity (%)	PPV (%)	NPV (%)
		Positive	Negative				
hCG Positive Urine Samples	50	50	0	100	-	100	-
hCG Negative Urine Samples	200	0	200	-	100	-	100

LIMITATIONS

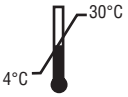
1. Very dilute specimens, as indicated by low specific gravity, may not contain representative levels of hCG. If pregnancy is still suspected, first morning urine suspension should be collected 48 hours later and tested.
2. False negative results may occur when the levels of hCG are below the sensitivity level of test. When pregnancy is still suspected, first morning urine suspension should be collected 48 hours later and tested.
3. A number of conditions other than pregnancy, including trophoblastic disease and non-trophoblastic neoplasms including testicular tumors, prostate cancer, breast cancer and lung cancer cause elevated levels of hCG. Therefore, the presence of hCG in urine should not be used to diagnose pregnancy unless these conditions have been ruled out.
4. Excessive Fluid intake should be avoided before testing. A 'Non-Pregnant' result may be obtained if the urine sample is too dilute.
5. This test strip is not reusable.

DISCLAIMER

The all precautions shall be taken to ensure the diagnostic ability and accuracy of this product. This product is utilized outside the control of manufacturer and distributors. The various factors including storage temperature, environmental conditions and procedure error may affect the results. This test provides presumptive diagnosis of pregnancy. A confirmed pregnancy diagnosis should only be made by a physician after all clinical and laboratory findings have been evaluated.

REFERENCES

1. Batzer FR. "Hormonal evaluation of early pregnancy", Fertil. Steril. 1980; 34(1): 1-13
2. Catt KJ, ML Dufau, JL Vaitukaitis "Appearance of hCG in pregnancy plasma following the initiation of implantation of the blastocyte", J. Clin.Endocrinol.Metab.1975;40(3):537-540
3. Braunstein GD,J Rasor, H.Danzer, D Adler, ME Wade "Serum human chorionic gonadotropin levels throughout normal pregnancy", Am. J. Obstet.Gynecol.1976;126(6): 678-681
4. Lenton EA, LM Neal, R Sulaiman "Plasma concentration of human chorionic gonadotropin from the time of implantation until the second week of pregnancy", Fertil. Steril. 1982; 37(6): 773-778
5. Steier JA, P Bergsjo, OL Myking "Human chorionic gonadotropin in maternal plasma after induced abortion, spontaneous abortion and removed ectopic pregnancy", Obstet.Gynecol. 1984; 64(3): 391-394.
6. Dawood MY, BB Saxena, R Landesman "Human chorionic gonadotropin and its subunits in hydatidiform mole and choriocarcinoma", Obstet.Gynecol. 1977;50(2): 172-18

IVD	In Vitro Diagnostic Use
	Manufacturer
	Manufacturing Date
	Expiry Date
LOT	Lot Number
	Store at 4°C to 30°C
	Single Use
	Number of tests in the pack
	Do not use if pouch or kit damaged
	This side Up
	Read package insert before use

MANUFACTURED BY

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