ImmunoScience INDIA

# ImmunoQuick

**Pregnancy**

## One Step Pregnancy Test - Device

**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**

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### 1. 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.

### 2. INTENDED USE

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

### 3. PRINCIPLE

The One Step Pregnancy Test is an immunoassay for the fast detection of hCG from human urine. The special membrane is placed in front of 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, 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 T-line, 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 are then bonded in the area of the control-line by the control antibodies immobilized there, 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.

### 4. 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
4. Plastic Dropper

### 5. MATERIALS NEEDED BUT NOT PROVIDED

1. Timer
2. Sample container
3. Disposable Gloves (optional)

### 6. 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.

### 7. WARNINGS

1. Do not reuse the test.
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 urine samples and used test 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. 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.

### 8. SPECIMEN COLLECTION

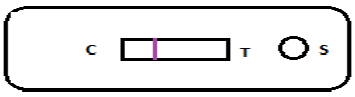
A urine specimen must be collected in a clean and dry container. A first morning urine specimen is preferred since it generally contains the highest concentration of hCG. However, urine specimens collected at any time of the day may be used.

### 9. TEST PROCEDURE

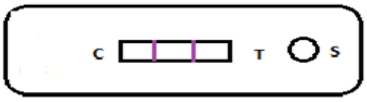
1. Allow the Pregnancy Test Device and urine sample to reach room temperature (20°C to 30°C) before opening the foil pouch.
2. Remove the Pregnancy Test Device from the pouch and use it as soon as possible.
3. Add two drops of urine sample in well 'S'.
4. Start the timer.
5. Read the result at 5 minutes. Do not read the result after 10 minutes.

### 10. INTERPRETATION OF RESULTS

**Negative:** A colored line appears at control side 'C' only.

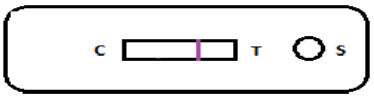



**Positive:** A distinct colored lines appears at control side 'C' and at test side 'T'.

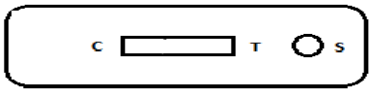



**Invalid:** The test should be considered invalid if,

A) No line appears at control side 'C' and line appears only at test side 'T'.




B) No line appears at control side 'C' and test side 'T'.




**NOTE:** The intensity of the colored line in the test line region (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.

## 11. 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 Device | | 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 - Device | | Sensitivity (%) | Specificity (%) | PPV (%) | NPV (%) |
|---|---|---|---|---|---|---|---|
| | | Positive | Negative | | | | |
| hCG Positive Urine Samples | 50 | 50 | 0 | 100 | - | 100 | - |
| hCG Negative Urine Samples | 200 | 0 | 200 | - | 100 | - | 100 |

## 12. 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.

## 13. 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.

## 14. 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 "Serumhuman 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):
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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| IVD | In Vitro Diagnostic Use |
| | Manufacturer |
| | Manufacturing Date |
| | Expiry Date |
| LOT | Lot Number |
| | Store at 4°C to 30°C |
| | Single Use |
| Σ | 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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