# HCG PREGNANCY STRIP (2-30°C)

| CATALOGUE NUMBER | KIT SIZE (TESTS) |
|---|---|
| RADHCG1 | 50 Tests |

**Intended Use:**
The hCG Pregnancy Strip (Urine) is a rapid chromatographic immunoassay for the qualitative detection of human chorionic gonadotropin in human urine, serum and plasma to aid in the early detection of pregnancy. This test is for *in vitro* diagnostic use by qualified personnel only.

**Summary:**
Human chorionic gonadotropin (hCG), a glycoprotein hormone produced by the developing placenta shortly after fertilization. hCG can normally be detected in both urine and serum or plasma as early as 7 to 10 days after conception. hCG levels continue to rise very rapidly, frequently exceeding 100mIU/ml by the first missed menstrual period, and peaking between 100,000 and 200,000mIU/ml around 10-12 weeks into pregnancy. The appearance of hCG in both the urine and serum/plasma 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.
The hCG Pregnancy Strip is a rapid test that qualitatively detects the presence of hCG in urine or serum or plasma specimen at the sensitivity of 10 mIU/ml. At the level of claimed sensitivity, the hCG Pregnancy Strip shows no cross-reactivity by the structurally related glycoprotein hormones hFSH, hLH and hTSH at high physiological levels.

**Test Principle:**
The hCG Pregnancy Strip uses a double antibody sandwich principle to detect hCG. The strip is coated with monoclonal anti-hCG antibody at the test zone and particles conjugated with anti-hCG antibody near the sample well. The test strip is dipped in urine, serum or plasma at the sample end from where the sample begins to migrate and reacts with the conjugated particles. The mixture continues to move up the membrane by capillary action and interacts with the anti-hCG coated in the test zone. If hCG is present in the sample in sufficient quantity, a coloured line develops at the test line. Absence of colour development at the test line indicates a negative result. To serve as a procedural control, a coloured line should always appear in the control line region indicating that proper volume of specimen has been added and membrane wicking has occurred.

**Reagents:**
The test contains anti-hCG antibody coated particles and anti-hCG coated on the membrane for the test line and goat polyclonal antibody and colloidal gold particles for the control line.

**Materials Provided**
Individually pouched test strips
Instructions for Use sheet

**Materials not provided:** Timer, specimen collection container

**Precautions:**
Read all the information in this Instructions for Use sheet before performing the test.
For professional in vitro diagnostic use only. Do not use after the expiry date.
The test should remain sealed in the pouch until ready to use. Do not use a strip if the foil pouch has been punctured or damaged.
All samples should be considered potentially hazardous and handled as if infectious.
The used test device should be discarded according to local regulations.

**Storage and Stability:**
Store as packaged at room temperature or refrigerated (2 - 30°C). The test is stable until the expiry date printed on the sealed pouch and label of the kit. The test must be kept sealed in the pouch until use. Do not freeze. Do not use after the expiry date.

**Sample Collection and Storage:**
Urine
Urine must be collected into a clean and dry container. The first morning urine sample is preferred since it generally contains the highest concentration of hCG; however, urine specimens collected at any time of the day may be used. Urine specimens exhibiting visible precipitates should be centrifuged, filtered, or allowed to settle to obtain a clear sample for testing. Samples can be stored for testing up to 48 hours at 2 - 8°C or freeze at -20°C or below for longer term storage. Frozen samples should be thawed and mixed thoroughly before testing.

Serum and Plasma
Collect samples by separation after venepuncture. Separate serum and plasma from red blood cells as soon as possible to avoid haemolysis. Use only clear, non-haemolysed samples. Serum and plasma samples may be stored at 2 - 8oC for up to 3 days. For long term storage, samples should be frozen below -20oC. Frozen samples must be completely thawed and mixed well prior to testing.

**Assay Procedure:**
1. Bring the device, samples and controls fully to room temperature (15 - 30°C) before starting any testing. Remove the test device from the sealed pouch, place it on a clean and level surface and use it immediately (or within one hour).
2. Remove the test from its sealed pouch, and place it on a clean, level surface. Label the strip with patient or control identification.
3. Indicator arrows pointing downwards direct the user for correct immersion of the strip into the sample. Lower the strip vertically into the urine, serum or plasma sample and allow sample to be absorbed for at least 15 seconds. Do not submerse the test strip past the maximum line on the strip.
4. Place the test strip on a non absorbent flat surface, start the timer and wait for coloured line(s) to appear. Read the result at 3 minutes for urine samples and at 5 minutes for serum and plasma sampels.

**NOTE:** A low endogenous hCG concentration might result in a weak line appearing at the test line after significant time has elapsed, therefore, do not interpret any result after 10 minutes.

**Interpretation of Results:**

**POSITIVE:** Two coloured lines appear on the membrane**.** One line appears in the control region (C) and another line appears in the test region (T). One line may be lighter than the other, they do not have to look the same. The result means that the patient is probably pregnant.

**NEGATIVE:** One coloured line develops, in the control region**.** There is no colour development in the test region. This means that the patient is probably not pregnant.

**INVALID:** The result is invalid if no coloured line appears at the control line, even if a line appears at the test line. The test should be repeated with a new test strip.

**Quality Controls:**
A procedural control is included in the test in which a coloured line should always develop at the Control line that confirms sufficient sample volume and correct procedural technique have taken place. A clear background is another internal procedural control check. If background reagent colour remains in the reading window and interferes with the ability to read the test result, the result may be invalid. It is recommended that a positive hCG control (containing 10-250 mIU/ml hCG) and a negative hCG control (containing 0 mIU/ml hCG) be evaluated to verify proper test performance for each new batch of tests.

**Limitations of the Test:**
1. The hCG Pregnancy Strip is a qualitative screening test, therefore, neither the quantitative value nor the rate of increase in hCG can be determined by this test.
2. Very dilute urine specimens, as indicated by a low specific gravity, may not contains representative levels of hCG. If pregnancy is still suspected, a first morning urine specimen should be collected 48 hours later and tested.
3. Very low levels of hCG (less than 50mIU/ml) are present in urine and serum or plasma specimen shortly after implantation. However, because a significant number of first trimester pregnancies terminate 1for natural reasons, a test result that is weakly positive should be confirmed by retesting with a first morning urine or serum or plasma specimen collected 48 hours later.
4. This test may produce false positive results. A number of conditions other than pregnancy, including trophoblastic disease and certain non-trophoblastic neoplasms including testicular tumour, 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.
5. This test may produce false negative results. False negative results may occur when the levels of hCG are below the sensitivity level of the test. When pregnancy is still suspected, a first morning urine specimen should be collected 48 hours later and tested. In case pregnancy is suspected and the test continues to produce negative results, see a physician for further diagnosis.
6. This kit is not intended to be used for the risk evaluation of trisomy 21.
7. This test provides a presumptive diagnosis for pregnancy. A confirmed pregnancy diagnosis should only be made by a physician after all clinical and laboratory findings have been evaluated.

**Expected Values:**
Negative results are expected in healthy non-pregnant women and healthy men. Healthy pregnant women have hCG present in their urine samples. The amount of hCG will vary significantly with gestational stage and between individuals. The hCG Pregnancy Strip has a sensitivity of 10 mIU/ml, and is capable of detecting pregnancy as early as 1 day after the first missed menstrual period.

**Performance Characteristics:**

Clinical Sensitivity and Specificity
A multi-centre clinical evaluation was conducted comparing the results obtained using the hCG Pregnancy Strip with a predicate hCG immunocromatograhic test for urine, serum and plasma. The study for urine samples involved 608 samples. The study for serum or plasma samples involved 308 samples. The results demonstrated a >99% overall accuracy of the hCG Pregnancy Strip device.

Results for urine samples

| Method | | Competitor hCG Rapid Test | | Total Results |
|---|---|---|---|---|
| hCG Pregnancy Strip | Results | Positive | Negative | |
| | Positive | 231 | 0 | 231 |
| | Negative | 0 | 377 | 377 |
| Total Results | | 231 | 377 | 608 |

Sensitivity: >99.9 % (98.7 – 100%) * *95% Confidence Intervals
Specificity: >99.9 % (99.2 – 100%) *
Accuracy: >99.9 % (99.5 – 100%) *

Results for serum or plasma samples

| Method | | Competitor hCG Rapid Test | | Total Results |
|---|---|---|---|---|
| hCG Pregnancy Strip | Results | Positive | Negative | |
| | Positive | 68 | 0 | 68 |
| | Negative | 0 | 240 | 240 |
| Total Results | | 68 | 240 | 308 |

Sensitivity: >99.9 % (95.7 – 100%) * *95% Confidence Intervals
Specificity: >99.9 % (98.8 – 100%) *
Accuracy: >99.9 % (99.0 – 100%) *

Cross-Reactivity
The test has been standardized to the W.H.O. International Standard. The addition of LH (300mIU/ml), FSH (1,000mIU/ml), and TSH (1,000µIU/ml) to negative (0mIU/ml hCG) and positive (10 mIU/ml hCG) samples showed no cross-reactivity in the hCG Pregnancy Strip test.

Precision
Intra-Assay
Within-run precision was determined using 10 replicates of four samples containing 0 mIU/ml, 10 mIU/ml, 100 mIU/ml and 250 mIU/ml of hCG. The negative and positive results were correctly identified 100% of the time.

Inter-Assay
Between-run precision was determined using the four samples of 0, 10, 100 and 250 mIU/ml of HCG in 10 assays on separate days. Three different lots of the hCG Pregnancy Device were tested. The specimens were correctly identified 100% of the time.

Interfering Substances
The following potentially interfering substances were added to hCG negative and positive specimens. None of the substances at the concentration indicated interfered in the correct results for the assay.

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| Acetaminophen | 20mg/dl | Caffeine | 20mg/dl |
| Acetylsalicylic Acid | 20mg/dl | Gentisic Acid | 20mg/dl |
| Ascorbic Acid | 20mg/dl | Glucose | 2mg/dl |
| Atropine | 20mg/dl | Haemoglobin | 1mg/dl |
| Bilirubin | 2mg/dl | | |

**References:**


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| REF | Catalogue number | | Temperature limitation |
| | Consult instructions for use | LOT | Batch code |
| IVD | *In vitro* diagnostic medical device | | Use by Date |
| | Manufacturer | | |

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**Prestige Diagnostics UK Ltd** 40 Ballymena Business Centre, Galgorm, Co. Antrim, BT42 1FL, United Kingdom. Tel: +44 (0) 28 2564 2100 www.prestigediagnostics.co.uk
info@prestigediagnostics.co.uk



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