HCG DEVICE (2-30°C)

CATALOGUE NUMBER	KIT SIZE (TESTS)
RADHCG2	20 Tests

Intended Use:
The hCG Device is a rapid chromatographic immunoassay for the qualitative detection of human chorionic gonadotropin in human urine, serum or plasma to aid in the early detection of pregnancy.

Summary:
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 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 or 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 Rapid Test Device is a rapid test that qualitatively detects the presence of hCG in urine or serum or plasma specimen with a sensitivity of 25mIU/ml. The test uses a combination of monoclonal and polyclonal antibodies to selectively detect elevated levels of hCG in urine or serum or plasma. At the claimed sensitivity concentration, the hCG Device shows no cross-reactivity from the structurally related glycoprotein hormones hFSH, hLH and hTSH at high physiological levels.

Test Principle:
The hCG Rapid Test Device comprises monoclonal anti-hCG antibody coated on the test line and anti-hCG antibody conjugated to particles coated near the sample well. The control band develops as a result of sample interaction with goat polyclonal antibodies conjugated to colloidal gold particles. The assay is conducted by adding urine, serum or plasma to the sample well and it begins to migrate and react with the conjugated particles. HCG present in the sample will bind to the antibody on the particles to form immunocomplexes. The mixture continues to move up along the membrane by capillary action and the immunocomplexes react with the anti-hCG antibody coated at the test line. If hCG is present in the sample in sufficient quantity, a coloured band 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 conjugated particles and anti-hCG coated on the membrane.

Materials Provided
Individually pouched test devices
Disposable pipettes
Instructions For Use sheet

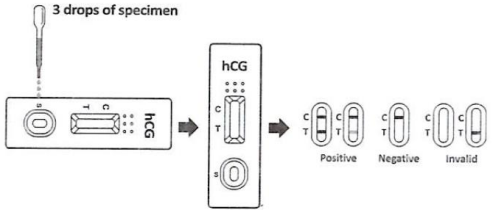
Materials not provided: Timer, specimen collection container

Precautions:
Please read all the information in this Instructions For Use sheet before performing the test.
For professional in vitro diagnostic use only (not self testing). The device should remain in the sealed pouch until use.
All specimens should be considered as potentially infectious and handled and disposed of as such.
Discard the device 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 must be collected into a clean and dry container. The first morning urine sample is optimal since it generally contains the highest concentration of hCG; however, urine specimens collected at any time of the day may be used. Urine samples 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.
Blood should be collected by separation after venepuncture into clean tubes with or without anticoagulants. Separate the serum or plasma as soon as possible to avoid haemolysis. Use only clear, non-haemolysed specimens. Serum and plasma samples may be stored at 2 - 8oC for up to 48 hours. 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. Hold the dropper vertically and transfer 3 drops of urine or serum or plasma (approximately 120 µl) to the sample well of the device and start the timer. Avoid trapping air bubbles in the sample well. See the illustration.
3. Wait for coloured line(s) to appear. Read the result at 3 minutes when testing a urine specimen, or at 5 minutes when testing a serum or plasma specimen. 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 25-250mIU/ml hCG and a negative hCG control with 0 mIU/ml hCG be tested as good laboratory practice to confirm the test procedure and to verify proper test performance.

Limitations of the Test:
1. The hCG Device is a qualitative test, therefore, neither concentration of or 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, serum and plasma shortly after implantation. However, because a significant number of first trimester pregnancies terminate for 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 or serum or plasma specimens 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 levels of hCG are present but 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. If pregnancy is suspected and the test continues to produce negative results, see a physician for further diagnosis.
6. There may be possible interference by human anti-mouse antibodies (HAMA) in samples. Specimens from patients who have received preparations of monoclonal antibodies for diagnosis or therapy may contain HAMA. Such specimens may cause false positive or false negative results.
7. This kit is not intended to be used for the risk evaluation of trisomy 21.
8. 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 and serum or plasma specimens. The amount of hCG will vary significantly with gestational stage and between individuals. The hCG Device has a sensitivity of 25 mIU/ml, and is capable of detecting pregnancy as early as 1 day after the first missed menses.

Performance Characteristics:

Clinical Sensitivity and Specificity
A clinical evaluation was conducted to compare results obtained using the hCG Device with another commercially available urine, serum or plasma hCG Rapid Test. The results demonstrated an overall accuracy of >99% for the hCG Device compared to the comparator test.

Results for Urine

Method		Comparator Test		Total Results
	Results	Positive	Negative	
hCG Device	Positive	231	0	231
	Negative	0	377	377
Total Results		231	377	608

Sensitivity: >99.9% (98.7% - 100%)*
Specificity: >99.9% (99.2% - 100%)*
Accuracy: >99.9% (99.5% - 100%)*

Results for Serum/Plasma

Method		Comparator Test		Total Results
	Results	Positive	Negative	
hCG Device	Positive	68	0	68
	Negative	0	240	240
Total Results		68	240	308

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

To validate the efficacy of the plasma matrix, paired samples of serum and plasma were collected from a panel of subjects. Serum samples were identified as positive or negative then results obtained for the paired plasma samples were compared.

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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Sensitivity
The hCG Device detects hCG at a concentration of 25mIU/ml or greater.
The test has been standardized to the W.H.O. International Standard.

Cross-Reactivity
The addition of LH (300mIU/ml), FSH (1,000mIU/ml), and TSH (1,000µIU/ml) to negative (0mlU/ml hCG) and positive (25mlU/ml hCG) specimens showed no cross-reactivity in the hCG Device.

Precision
Intra-Assay precision was determined using 10 replicates of four specimens containing 0, 25, 100 and 250mIU/ml of hCG. The negative and positive values were correctly identified 100% of the time.

Inter-Assay precision was determined by using the same four specimens 0, 25, 100 and 250mIU/ml of hCG in 10 separate assays. Three different batches of the hCG 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.

Acetaminophen	20mg/dl	Caffeine	20mg/dl
Acetylsalicylic Acid	20mg/dl	Gentisic Acid	20mg/dl
Ascorbic Acid	20mg/dl	Glucose	2g/dl
Atropine	20mg/dl	Haemoglobin	1mg/dl
Bilirubin	2mg/dl	Bilirubin (serum or plasma)	40mg/dl
Triglycerides (serum or plasma)		1,200mg/dl	

None of the substances interfered in the expected results for the hCG Device assays at the concentration tested.

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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