hCG Pregnancy Rapid Test

Serum/Plasma/Whole Blood

The hCG Serum/Plasma/Whole blood is a rapid immunoassay for the qualitative detection of human chorionic gonadotropin (hCG) in human Serum/Plasma/Whole blood and serum as an aid for the early detection of pregnancy.
For professional / self and in-vitro diagnostic use only.

ORDER INFORMATION

Pack Size	REF
01 Test	PHWB 01
05 Tests	PHWB 05
10 Tests	PHWB 10
25 Tests	PHWB 25
50 Tests	PHWB 50

CLINICAL SIGNIFICANCE

Human chorionic gonadotropin (hCG) is a glycoprotein secreted by trophoblast cells during pregnancy. This hormone interacts with ovary specific receptors and promotes the maintenance of the corpus luteum for the maternal recognition of pregnancy. This allows the corpus luteum to secrete progesterone which play key roles to prepare uterus for fetus growth. The possible detection of hCG in Serum/Plasma/whole blood and serum as early as 7 to 10 days after conception makes it an excellent marker for confirming rapidly pregnancy.
The hCG Serum/Plasma/whole blood uses highly specific monoclonal antibodies targeting hCG in human Serum/Plasma/whole blood and serum. Its detection at a level above 25 mIU/mL is used to detect early pregnancy.

PRINCIPLE

The hCG Serum/Plasma/Whole blood uses monoclonal hCG antibodies to selectively detect elevated levels of hCG in Serum/Plasma/Whole blood and serum. The assay is conducted by dispensing an adequate volume of the blood or serum specimen into the sample well of the cassette using the lancet and the micropipette. A buffer solution is added to the well to facilitate the reagent capillary action across the strip held in the cassette. The sample then migrates across a membrane toward the results window where the labeled hCG complex is captured at a test line region containing immobilized monoclonal anti-hCG. The appearance of two red lines, one at test region (T) and the other at the control region (C) indicates the presence of hCG in the sample. A colored line should always appear in the control line region (marked "C"), indicating that the proper volume of specimen has been added and that the test worked correctly. If hCG is absent or below the detection limit (25 mIU/mL), only the control line will appear in the result window.

KIT COMPONENTS

• Test Cassettes • Assay buffer • Droppers • Alcohol Swab • Lancet • Product insert

MATERIALS REQUIRED BUT NOT PROVIDED

• Micropipette • Timer

PRECAUTIONS

1. For professional *in vitro* diagnostic use only. Do not use after the expiration date.
2. Wear protective gloves while handling specimens wash thoroughly afterwards.
3. The device is sensitive to humidity as well as heat. Therefore, take out the device from seal pouch before test.
4. Do not mix reagents from different lot.
5. Dispose all the samples and kits properly as per the instruction after test in accordance in GLP.
6. Follow the testing procedure exactly as mention in the insert.

STORAGE AND STABILITY

1. The kit can be stored at room temperature or refrigerated (2-30°C). The test device must remain in the sealed pouch until use. DO NOT FREEZE.
2. Do not use beyond the expiration date.
3. Do not use the test kit, if the pouch is damaged or seal is broken.

SPECIMEN COLLECTION & PREPARATION

The hCG Pregnancy Rapid Test (Whole Blood/Serum/Plasma) can be performed using whole blood, serum and plasma specimen.

- **Serum (S):** Collect the whole blood into a collection tube (NOT containing anticoagulants such as heparin, EDTA, and sodium citrate) by venipuncture, leave to settle for 30 minutes for blood coagulation and then centrifuge blood to get serum specimen of supernatant.
- **Plasma (P):** Collect the whole blood into a collection tube (containing anticoagulants such as EDTA K2, Heparin sodium, Citrate sodium and Oxalate potassium) by venipuncture and then centrifuge blood to get plasma specimen.
- **Whole Blood (WB):** Both Fingerstick Whole Blood and Venipuncture Whole Blood can be used.

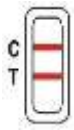
DIRECTIONS FOR USE

Allow the test device, specimen and/or buffer to equilibrate at room temperature (15-30°C) before testing.

1. Bring the pouch to room temperature before opening it. Remove the test cassette from the sealed pouch and use it within 1 hour.
2. Place the cassette on a clean and level surface.
3. **For Serum or Plasma specimen**: Hold the dropper vertically and transfer 1 drop of serum or plasma (approximately 25µL) and add 1 drop of buffer (approximately 40 µL) into the specimen well, and start the timer. See illustration below.
   For Venipuncture Fresh Whole Blood specimen: Hold the dropper vertically and transfer 1 drop of whole blood (approximately 25 µL) to the specimen well, then add 1 drop of buffer (approximately 40 µL), and start the timer. See illustration below.
   For Fingerstick Fresh Whole Blood specimen: Take sample using sample dropper and transfer approximately 25 µL (1 drops) of fingerstick whole blood specimen to the specimen well of test cassette, then add 1 drop of buffer (approximately 40 µL) and start the timer. See illustration below.
4. Wait for the colored line(s) to appear. Read results at 05 minutes.
   Note: Do not interpret the result after 10 minutes.

INTERPRETATION OF RESULT

Positive
Both test line (T) and control line (C) appear in the result window.



Note: The intensity of the color in the test line regions may vary depending on the concentration of the hCG in the sample. A faint line (C or T) should be considered as positive result.

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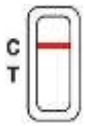
Serum/Plasma/Whole Blood

Negative

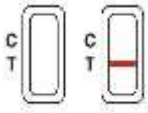
Only the control line (C) appears in the result window. The absence of a test line (T) indicates a negative result.



Invalid

If the control line (C) does not appear, the test result is invalid.

Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test with a new test.



Quality Control

Internal procedural controls are included in the test. A colored line appearing in the control region (C) is an internal procedural control. It confirms sufficient specimen volume and correct procedural technique. Control standards are not supplied with this kit. However, it is recommended that positive and negative controls be tested as a good laboratory practice to confirm the test procedure and to verify proper test performance.

Limitations of the Test

1. If a negative result is obtained although pregnancy is still suspected, the hCG level in the specimen may be below the detection limit of the test (25 mIU/mL) It is recommended to repeat the test 24 to 48 hours later.
2. Very low levels of hCG are present in Serum/Plasma/Whole blood specimen shortly after implantation. However, because a significant number of first trimester pregnancies terminate for natural reasons, a test result weakly positive should be confirmed by retesting 48 hours later.
3. A number of conditions other than pregnancy, including trophoblastic disease, testicular tumors, prostate cancer, breast cancer and lung cancer cause elevated levels of hCG. Therefore, the presence of hCG in Serum/Plasma/whole blood specimen should not be used to diagnose pregnancy unless these conditions have been ruled out.
4. This test provides a presumptive diagnosis for pregnancy. A confirmed pregnancy diagnosis should be made by a physician after all clinical and laboratory findings have been evaluated.

Performance characteristics

A total of 200 specimens were collected and tested by HCG Pregnacy Rapid Test and a commercial HCG Pregnancy Rapid Test as reference. Comparison for all subjects is showed in the following table.

Specimen	Positive	Negative	Sensitivity and Specificity
Positive	99	01	99.0 %
Negative	01	99	99.0 %

Clinical evaluation

hCG Serum/Plasma/whole blood was evaluated prospectively and independently in early pregnancy units on 200 patients. Considering the claimed limit of detection, the test demonstrated 99.0% and 99.0% Positive Predictive Value and Negative Predictive Value respectively.

Limit of detection

The limit of detection of hCG Serum/Plasma/whole blood is 25 mIU/mL.

Interfering substances

The following potentially interfering substances were added to hCG negative and positive (25 mIU/mL) specimens.
None of the substances at the concentration tested interfered in the assay.

Interfering substances	Concentration level
LH	300 mIU/mL
FSH	1000 mIU/mL
TSH	1000 mIU/mL
Acetylsalicylic Acid	20 mg/dL
Bilirubin	20 g/dL
Gentisic Acid, Atropine, Ascorbic Acid	20 mg/dL
Caffeine	20 mg/dL
Hemoglobin	1 g/dL
Glucose	2 g/dL

Bibliography:

1. Batzer FR. Fertil Steril. Hormonal evaluation of early pregnancy. 1980 Jul; 34(1): 1-13.
2. Catt KJ, Dufau ML, Vaitukaitis JL. Appearance of hCG in pregnancy plasma following the initiation of implantation of the blastocyst. J Clin Endocrinol Metab. 1975 Mar; 40(3): 537-40.
3. Braunstein GD, Rasor J, Danzer H, Adler D, Wade ME. Serum human chorionic gonadotropin levels throughout normal pregnancy. Am J Obstet Gynecol. 1976 Nov 15; 126(6): 678-81.
4. Lenton EA, Neal LM, Sulaiman R. Plasma concentrations of human chorionic gonadotropin from the time of implantation until the second week of pregnancy. Fertil Steril. 1982 Jun; 37(6): 773-8.
5. Uotila M, Ruoslahti E, Engvall E. Two-site sandwich enzyme immunoassay with monoclonal antibodies to human alpha-fetoprotein. J Immunol Methods. 1981; 42(1): 11-5.

GLOSSARY OF SYMBOL

	Consult Instruction for Use
REF	Catalog Number
	Store between
	Manufacturer
	Keep away from sunlight

India office
BIOBOON BIOTECH INDIA LLP
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2nd floor, Above D'mart shopping mall
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