PARAMCARE LIFE SCIENCES PVT. LTD.
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PARAMCARE™

hCG Pregnancy Rapid Test

Serum/Plasma/Whole Blood

Intended use

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 as an aid for the early detection of pregnancy.
For professional / self and in-vitro diagnostic use only.

Summary

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. Its detection at a level above 25 mIU/mL is used to detect early pregnancy.

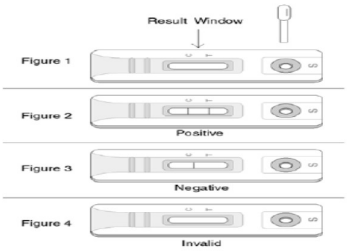
Test principle

The hCG Serum/Plasma/Whole blood uses monoclonal hCG antibodies to selectively detect elevated levels of hCG in Serum/Plasma/Whole blood. 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

Reagents and material provided

Each kit contains:

• Test Cassettes • Droppers •Assay Buffer • Package Insert • Alcohol Swab • Lancet



Precautions

- For Professional in vitro diagnostic use only.
- Do not use after the expiration date.
- Do not use test if pouch is torn or damaged.
- The test device should remain in the sealed pouch until use.
- Perform the test quickly after opening the aluminum pouch.
- Wear protective clothing such as laboratory coat, disposable gloves and eye protection when specimens are assayed.
- Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout all procedures and follow the standard procedures for proper disposal of specimens.
- Make sure all collected blood is transferred on test strip. Too much or too little sample size may lead to deviation of results.
- Do not use the buffer of another kit.
- Do not eat, drink or smoke in the area where the specimens or kits are handled.
- The test must be placed on a flat surface while waiting for the results.

Material required but not provided

- Timer
- Disposable gloves
- Specimen collection containers
- Calibrated micropipette for 25µL
- The test device should not be reused.
- The test device should be discarded in a suitable biohazardous waste container after testing according to local regulations.

Storage and stability

Store as packaged in the sealed pouch between 4 and 30°C. The test is stable through the expiration date printed on the sealed pouch. The test must remain in the sealed pouch until use. **DO NOT FREEZE**. Do not use beyond the expiration date. If the kit has been stored at 4-8°C, bring it to room temperature (15-25°C) for at least 10 minutes.

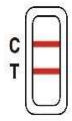
Specimen collection

Fresh capillary blood from finger prick should be used as a test specimen. However, serum is a suitable alternative specimen. The specimen should be collected in a clean glass or plastic container.

Procedure

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 Fingerstick Whole Blood specimen:** Take sample using sample dropper and transfer approximately 25 µL (1 drop) 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.
4. **For Venipuncture Whole Blood specimen**: Hold the dropper vertically and transfer 1 drop of whole blood (approximately 25µL) to the specimen well, then add 1 drop of buffer (approximately 40 µL) and start the timer
5. **For Serum or Plasma specimen**: Place the cassette on a clean and level surface. For Serum or Plasma specimen: Hold the dropper vertically and transfer 1 drop of serum or plasma (approximately 25 µL) to the specimen well, then add 1 drop of buffer (approximately 40 µL) and start the timer
6. Wait for the colored line(s) to appear. Read results at 5 minutes.
   Note: Do not interpret the result after 10 minutes.

Interpretation of results

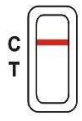


Positive

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

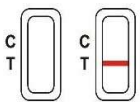
NOTE:

- 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 (T) should be considered as positive result.
- Neither the quantitative value nor the rate of increase in hCG can be determined by this qualitative test.



Negative

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



Invalid

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. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

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

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

1. Sensitivity and specificity

Method		Other hCG Rapid Test		Total Results
hCG Pregnancy Rapid Test	Results	Positive	Negative	
	Positive	163	0	163
	Negative	0	280	280
Total Results		163	280	443

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

2. Clinical evaluation

hCG Serum/Plasma/Whole blood was evaluated prospectively and independently in early pregnancy units on 543 patients. Considering the claimed limit of detection, the test demonstrated 100% and 99.3% Positive Predictive Value and Negative Predictive Value respectively.

3. Limit of detection

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

4. Hook Effect

No hook effect observed up to 500,000 mIU/mL.
The test bands may appear with a less intensive color than expected for samples containing high levels of hCG> 500,000 mIU/mL.

5. Repeatability and Reproducibility

The repeatability and reproducibility of the hCG Serum/Plasma/Whole blood was evaluated with positive and negative samples. No significant difference was observed between batches, operators and inter-run results.

6.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
Rheumatoid Factor	174 IU/mL
Human anti-mouse antibodies	715 ng/mL
Antinuclear antibodies (centromere type speckled nucleolar and homogeneous)	Titer > 1280
Caffeine	200 µg/mL

Bibliography:

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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. Engvall E. Enzyme immunoassay ELISA and EMIT. Methods Enzymol. 1980; 70(A): 419-39.
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GLOSSARY OF SYMBOL

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

Paramcare Life Sciences Private Limited, G/F-12/13, Evershine-2, Survey No. 307/3/1, Balitha N.H No 48, Vapi, Valsad, Gujarat, 396191.
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