Finecare™ β-hCG Rapid Quantitative Test

Catalog No. W225

INTENDED USE

The Finecare™ β-hCG (β-human chorionic gonadotropin) Rapid Quantitative Test along with Finecare™ FIA Meter is a fluorescence immunoassay that quantifies β-hCG concentration in the whole blood/ serum/ plasma. The test is used as an aid in the early detection of pregnancy.
-Fluorescence immunoassay
-Pregnancy test

For in vitro diagnostic use only. For professional use only.

SUMMARY

Human chorionic gonadotropin (hCG) is a glycoprotein with a molecular weight of 38000, secreted by the placenta. Like other glycoprotein hormones (hLH, hTSH and hFSH), hCG contains two different subunits, an α- and a β-chain, linked by noncovalently bindings. The primary structures of the α subunits of these hormones are virtually identical, while their β subunits, responsible for the immunological and biological specificity, are different. Thus a specific determination of hCG can only be made by the determination of its β component. The measured hCG content results almost exclusively from intact hCG molecules but there can be a contribution, albeit a usually negligible fraction of the total, from the freeβ-hCG subunit.

hCG appears in the serum of pregnant women five days after the implantation of blastocyst and its concentration continually increases until the third month of the pregnancy. The maximum concentration can reach values up to 100 IU/ml. Then the hormone level drops to 25 IU/ml and stays around this value until the last trimester.

Elevated hCG concentrations can be seen in the case of trophoblastic and nontrophoblastic neoplasia, and choriocarcinoma.

Ectopic hormone production which is frequently associated with the metastatic breast cancer and with tumors of the liver, stomach, lung, and uterus often results in the elevated hCG concentration both in men and in non-pregnant women.
Normal reference values: <5mIU/ml

Weeks of Pregnancy	Range mIU/mL	Weeks of Pregnancy	Range mIU/mL
3	5.8-71.2	10	46,509-186,977
4	9.5-750	12	27,832-210,612
5	217-7138	14	13,950-62,530
6	158-31,795	15	12,039-70,971
7	3697-163,563	16	9040-56,451
8	32,065-149,571	17	8175-55,868
9	63,803-151,410	18	8099-58,176

Notice: Individual reference range is suggested to be established for each laboratory.

PRINCIPLE

The Finecare™ β-hCG (β-human chorionic gonadotropin) Rapid Quantitative Test is based on fluorescence immunoassay technology. The Finecare™ β-hCG Rapid Quantitative Test uses a sandwich immunodetection method, when sample is added to the sample well of the test cartridge, the fluorescence-labeled detector β-hCG antibody on the membrane binds to β-hCG antigen in blood specimen. As the sample mixture migrates on the nitrocellulose matrix of test strip by capillary action, the complexes of detector antibody and β-hCG are captured to β-hCG antibody that has been immobilized on test strip. Thus the more β-hCG antigen is in blood specimen, the more complexes are accumulated on test strip. Signal intensity of fluorescence of detector antibody reflects amount of β-hCG captured and Finecare™ FIA Meter shows β-hCG concentrations in blood specimen. The default results unit of Finecare™ β-hCG Rapid Quantitative Test is displayed as XXX mIU/mL from Finecare™ FIA Meter. The working range and the detection limit of the β-hCG Test system are 2-200,000 mIU/mL and 2 mIU/mL.

PRECAUTIONS

1. This kit is for in vitro diagnostic only. Do not swallow.
2. Do not mix components from different kit lots.
3. Do not use test kit beyond the expiration date.
4. Do not use test cartridge if its lot #does not match ID chip# that is inserted onto the instrument.
5. The Finecare™ β-hCG Rapid Quantitative Test kit is only operational in the Finecare™ FIA Meter.
6. Do not use the test cartridge if the pouch is punctured or not well sealed.
7. The test cartridge and meter should be used away from vibration and magnetic field. During normal usage, the meter itself may cause vibration, which should be regarded as normal.
8. Use separate clean pipette tips and detector buffer vials for different specimens.
9. Blood specimens, used test cartridge, pipette tips and detector buffer vials should be handed and disposable in accordance with standard procedures and relevant regulations observed by microbiological hazard materials.
10. The results should be interpreted by the physician along with clinical findings and other laboratory test results.

MATERIAL

Material Provided

Test Cartridge	25
Test Cartridge ID Chip	1
Detector buffer	25
Leaflet with instructions for use	

Material Required But Not Provided

1. Finecare™ FIA Meter
2. Transfer Pipette Set (20μL, 75 μL size)
3. Specimen Collection Containers
4. Timer

STORAGE AND STABILITY

1. Store the detector buffer at 4～30℃. The buffer is stable up to 18 months.
2. Store Finecare™ β-hCG Rapid Quantitative Test Cartridge at 4～30℃, shelf life is up to 18 months.
3. Test Cartridge should be used within 1 hour after opening the pack.

SPECIMEN COLLECTION AND PREPARATION

The test can be performed with serum or plasma or whole blood.

For Whole Blood Collected by Venipuncture:

1. Using standard phlebotomy procedure, collect a venipuncture whole blood specimen using a blood collection tube with suitable anticoagulant (EDTA recommended)
2. It is recommended that specimens should be tested immediately. Do not leave the specimens at room temperature for prolonged periods. If the specimens are not tested immediately, they should be stored at 2℃～8℃.
3. It's not suggested to test the whole blood samples which have been stored at 2 ℃～8℃ for more than 2 days.

For Serum and Plasma:

1. Using standard phlebotomy procedure, collect a venipuncture whole blood specimen using a blood collection tube. If collecting plasma use a blood collection tube containing suitable anticoagulant (EDTA recommended).
2. Separate the serum/plasma from blood as soon as possible to avoid hemolysis.
3. Test should be performed immediately after the specimens have been collected. Do not leave the specimens at room temperature for prolonged periods. Specimens may be stored at 2℃～8℃ for up to 3 days. For long-term storage, specimens should be kept below -20℃.

TEST PROCEDURE

Refer to Finecare™ FIA Meter Operation Manual for the complete instructions on use of the Test. The test should be operated in room temperature.

Step1: Preparation

Before testing, activate "use" in setting then save it.
Check/insert ID Chip onto the equipment.
Take out one tube of buffer from refrigerator and balance it at room temperature

Step2: Sampling

Draw 20μL of whole blood, serum/plasma with a transfer pipette and add it to the buffer tube.

Step3: Mixing

Mix well the specimen with buffer for 1 minute by tapping or inverting the tube.

Step4: Loading

Take 75 μL of sample mixture and load it onto the sample well of the Test Cartridge.

Step5: Testing

1. Finecare™ FIA meter:
   Standard test: Insert the Test Cartridge onto the Test Cartridge Holder and click “Test”. 15 minutes later, choose the sample type, then the result will show in the display and print out when click “print”.
   Quick test: Put the Test Cartridge on the operation platform.15 minutes later, insert the Test Cartridge onto the Test Cartridge Holder and click “Test”, choose the sample type, then the
   result will show in the display and print out when click “print”.
2. Finecare™ multi-channel FIA meter:
   Insert the Test Cartridge onto the Test Cartridge Holder and click “Test”. 15 minutes later, the result will show in the display and print out when click “print”.

Please refer to the **Operation** in user manual of Finecare™ FIA Meter for details.

Interpretation of test results

β-hCG quantitative test results indicate whether test targets are pregnant or not. A less than 5 mIU/ml β-hCG concentration outcome interprets a negative result. If test results are higher than 25 mIU/ml, it will illustrate that samples are positive. Test concentration results between 5 and 25 mIU/ml will be reported with concentrations only. No interpretation will be reported for these results.

Note:

1. Test results should be used with other clinical information, such as medical history, symptoms, other tests, and clinical performance. If the results fail to meet clinical status, please use other hCG tests, such as urine hCG test.

2. If you have a positive result (≥ 25 mIU/ml), further detections and tests might be required. Also, we suggest you ask your doctor for more advices.

3. If the test result is between 5 and 25 mIU/ml, the chance of pregnancy cannot be rule out. There might be an early pregnant. However, other factors that might infect and increase the concentration cannot be eliminated as well.

4. Under some special circumstance, hCG concentration is higher than normal value. Unknown interference is included but not limited as below:
   heterophilic antibodies
   non-specific protein interaction
   hCG analog

5. Medicines and other internal substances may always interfere test results.
6. High concentration of hCG might relate to pathologic status, for instance, trophoblast cell and non-trophoblast cell tumor.

7. No matter how low the result display, the possibility of pregnancy cannot be excluded. Healthy, not pregnant woman could have low level hCG result. The hCG concentration in a pregnant woman can be double after 48 hours. Therefore, patient with low hCG result need to retest after 48 hours.

8. Menopausal woman might give a week positive result due to low level hCG. Please do a second test after 48 hours or use other hCG tests.

9. Because of the high degree of sensitivity of the assay, specimens tested as positive during initial days after conception may later be negative due to natural termination of the pregnancy. Natural termination occurs in 22% of clinically unrecognized pregnancies and 31% of pregnancies overall. It is good laboratory practice to resample and retest weak positive results after an additional 48 hours.

QUALITY CONTROL

Each Finecare™ β-hCG Rapid Test Cartridge contains internal control that satisfies routing quality control requirements. This internal control is performed each time a patient sample is tested. This control indicates that the test cartridge was inserted and read properly by Finecare™ FIA Meter. An invalid result from the internal control causes an error message on Finecare™ FIA Meter indicating that the test should be repeated.

LIMITATIONS OF PROCEDURE

1. This test has been developed for testing human whole blood, serum and plasma specimen.
2. The false positive results include cross-reactions with some components of serum from individual to antibodies; and non-specific adhesion of some components in human blood that have similar epitopes to capture and detector antibodies. In the case of false negative results, the most common factors are: non-responsiveness of antigen to the antibodies by that certain unknown components are masking its epitope, such that antigen cannot be seen by the antibodies; instability of β-hCG antigen, resulting in degradation with time and, or temperature, such that they become no longer recognizable by antibodies; and degraded other test components. The effectiveness of the test is highly dependent on storage of kits and sample specimens at optimal conditions.
3. Plasma using anticoagulants (e.g. heparin or citrate) other than EDTA has not been evaluated in Finecare™ β-hCG Rapid Test and thus should not be used.
4. Other factors may interfere with Finecare™ β-hCG Rapid Quantitative Test and may cause erroneous results. These include technical or procedural errors, as well as additional substances in blood specimens.

PERFORMANCE CHARACTERISTICS

Accuracy

Test cartridges from same batch were tested with β-hCG control of three different levels of concentration, mean and Bias% were calculated, Bias% was within 10%.

Assay Range and Detection Limit

- **Assay Range**: 2-20,0000 mIU/mL
- **Detection Limit:** 2mIU/ml

Linearity

A serial concentration of β-hCG controls at 2mIU/ml～200000mIU/ml were tested, the Correlation Coefficient (R) is ≥ 0.99.

Precision

Intra-Lot Precision

Within-run precision has been determined by using 10 replicates from same batch to test with β-HCG control. C.V. is ≤ 15%.

Inter-Lot Precision

Between-run precision has been determined by using 3 replicates from random 3 continuous batches to test with β-hCG control. C.V. is ≤15%.

BIBLIOGRAPHY OF SUGGESTED READING

1. Braunstein GD, Rasor J，Danzer H，et al. Serum human chorionic gonadotropin levels throughout normal pregnancy[J]. American journal of obstetrics and gynecology，1976，126(6)：678-681.
2. Saxena BB，Landesman R. Diagnosis and management of pregnancy by the radioreceptor assay of human chorionic gonadotropin[J]. American journal of obstetrics and gynecology，1978，131(1)：97-107.
3. Ross GT. Clinical relevance of research on the structure of human chorionic gonadotropin[J]. Am J ObstetGynecol，1977，129(7)：795-808.
4. Kadar N，Caldwell BV，Romero R. A Method of Screening for Ectopic Pregnancy and Its Indications[J]. ObstetGynecol 1981，58：162-166.
5. Kadar N，DeVore G，Romero R. Discriminatory hCG Zone: Its Use in the Sonographic Evaluation for Ectopic Pregnancy[J]. ObstetGynecol 1981，58：156-161.
6. Lab Report For Physicians. Standardization of Human Chorionic Gonadotropin. December 1985，7：92-94.

IVD	In Vitro Diagnostic Use		See Instruction for Use		Expiry Date
Σ	Tests per Kit		Manufacturing Date		Keep Dry
LOT	Batch Number	EC REP	Authorized Representative		Keep away from Sunlight
4°C 30°C	Store between 4～30℃				

Guangzhou Wondfo Biotech Co., Ltd.
No.8 Lizhishan Road, Science City, Luogang District, 510663, Guangzhou, P.R.China

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