β-HCG Rapid Quantitative Test

Catalog No.: BT2202

INTENDED USE

The Biotime β-HCG (Total Human chorionic gonadotropin) Rapid Quantitative Test is intended to quantify the concentration of β-HCG in human serum or plasma on Biotime FIA Analyzers by fluorescent immunoassay. The test is used as an aid detection of early pregnancy, embryonic development and ectopic pregnancy.
-Fluorescent immunoassay
-Early pregnancy, embryonic development and ectopic pregnancy
For in vitro diagnostic use only. For professional use only.

INTRODUCTION

β-HCG Rapid Quantitative Test is used to detect the concentration of β-HCG in human serum or plasma.
HCG (Human chorionic gonadotropin) is a kind of glycoprotein homone secreted by placental trophoblast cells. It can maintain the level of corpus luteum and decrease the activity of mother lymphocyte, which prevent the embryo from immune rejection. HCG consists of an α subunit and a β subunit. The concentration of β subunit of HCG is used to represent the concentration of HCG in human blood. The concentration of β-HCG is up to 27000-210000mIU/mL from the eighth week to the twentieth week of pregnancy. It will drop down to 8000-60000mIU/mL at the eighteenth week of pregnancy. The detection of β-HCG can represent the summation of HCG and free β-HCG[1-3].

PRINCIPLE

This test kit is based on fluorescent lateral flow immunoassay. While the sample and the buffer are mixed and applied into the test cartridge, the β-HCG in the sample and the mouse anti-β-HCG monoclonal antibody labeled with fluorescent microsphere form a reaction intermediate complex. During lateral flow, the intermediate complex moves along with the nitrocellulose membrane to a detection line (T-line: coated with β-HCG specific monoclonal antibodies). The intermediate complex will be captured by T-line to form final reaction compound sandwich. Thus the fluorescent signal on detection line is positively correlated with the concentration of β-HCG in human serum or plasma.

The fluorescent signal from microspheres of compound sandwich will be detected and calculated according to the calibration curve (in SD card provided with the reagents) to represent the concentration of β-HCG in human serum or plasma.

PRECAUTIONS

1. This reagent is used for in vitro diagnosis only. Please do not use expired products.
2. All blood samples (including the remaining samples after testing), used reagents and waste should be treated as infectious materials.
3. The reagent is for single time use. Once the pouch is opened, it should be used within 30 minutes to avoid failure caused by the moisture absorption.
4. While using the test cartridge and instruments, vibration and strong electromagnetic environment should be avoided.
5. Lot number of buffers and test cartridges must be matched.
6. Do not insert the cartridges that are contaminated with blood or other liquids on the surface. Oherwise, it may cause damages to the instrument.

MATERIAL

Material Provided
1. Test cartridge 25 tests/kit
2. Detector buffer 25 tubes/kit
3. SD Card 1 piece/kit
4. Instructions for use 1 copy/kit

Material Required But Not Provided
1. Biotime FIA Analyzer
2. Transfer Pipette Set and pipette tips (range 5~50μL and 10~100μL)
3. Specimen collection containers
4. Timer

STORAGE AND STABILITY

1. Store the detection buffer at 2-8℃, the shelf life is 24 months.
2. Store the test cartridge at 2-30℃, the shelf life is 24 months.
3. Test Cartridge should be used within 30 minutes after opening the pouch.

SPECIMEN COLLECTION AND PREPARATION

1. The test can be performed with serum or plasma specimen.
2. The specimen collection container should be EDTA-K2 tube for plasma and immune tube or pro-coagulant tube for serum.
3. The collection of the sample: the venipuncture for blood collection method referring to the National Clinical Laboratory Procedures, if the sample can't be detected in time, it can be stored in refrigerator at 2-8℃ for no more than 7 days，or at -20℃ for no more than 6 months. Samples should be recovered to the room temperature before test.
4. Separate the serum or plasma from blood as soon as possible to avoid hemolysis.

TEST PROCEDURE

Please refer to operation manual of Biotime FIA analyzers for details.
The test should be operated at room temperature (~25℃).
Step 1: Preparation
Check/insert SD card into the equipment.
Take out one tube of buffer from refrigerator and balance it to room temperature.
Step 2: Sampling
Take 20μL of serum or plasma with a transfer pipette and add it into the buffer tube.
Step 3: Mixing
Mix well the specimen with buffer by tapping or inverting the tube.
Step 4: Loading
Take 80μL of sample mixture and load it into the well of the test cartridge.
Note: Step 2 to step 4 should be completed within 1 minute to ensure the accuracy of the test results.
Step 5: Testing
Ensure that there are no air bubbles. Immediately insert the test cartridge into analyzer and incubate for 10 minutes.
NOTE: Please refer to the operation manual of a specific model of the analyzer for details.

REFERENCE INTERVAL

Normal reference interval: <10.00mIU/mL.
The specific normal range of the pregnancy cycle testing is shown in the following table:

Gestational weeks	reference range （mIU/mL）	Gestational weeks	reference range （mIU/mL）
3 Weeks	10-71.2	4 Weeks	15- 750
5 Weeks	217-7138	6 Weeks	306-31796
7 Weeks	3697-163563	8 Weeks	32065-149571
9 Weeks	63803-151410	10 Weeks	46509-186977
11Weeks	32127-204743	12 Weeks	27832-210612
14 Weeks	13950-62530	15 Weeks	12039-70971
16 Weeks	9040-56451	17 Weeks	8175-55668
18 Weeks	8099-58176		

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

LIMITATIONS OF PROCEDURE

1. The test sample should be serum or plasma specimen.
2. Human anti-mouse antibody (HAMA) may be presented in patients who have received immunotherapy with a murine monoclonal antibody. This kit has been specially designed to minimize the effect of these antibodies on the test results. However, the test result must be carefully evaluated when patients are known to have these antibodies [4-5].
3. Other factors also can induce the false results, including the technology, operational error and other sample factors.

PERFORMANCE CHARACTERISTICS

Accuracy
β-HCG control materials with two different concentrations were tested by every lot of Test Cartridges, and the deviations were within ±15%.
Assay Range: 5.0-200000.0mIU/mL
The Lowest Detection Limit: 5.0mIU/mL
Linearity
A serial concentrations of β-HCG reference materials at 5.0-200000.0mIU/mL were tested, and the correlation coefficient (R) is ≥ 0.9900.
Precision
Intra-lot Precision
Intra-lot precision was determined by testing of β-HCG reference materials using 10 test cartridges from the same lot. The C.V. is ≤ 15%.
Inter-lot Precision
Inter-lot precision was determined by testing of β-HCG reference materials using 30 test cartridges from 3 consecutive batches randomly (10 test cartridges from each lot). The C.V. is ≤ 20%.
Specificity
The concentration of β-HCG is not greater than 5.0mIU/mL when the concentration of LH is 300mIU/mL.
The concentration of β-HCG is not greater than 5.0mIU/mL when the concentration of FSH is 500mIU/mL.
The concentration of β-HCG is not greater than 5.0mIU/mL when the concentration of TSH is 1000μIU/mL.

SYMBOLS

Symbol	Description	Symbol	Description
	Catalogue number		In vitro diagnostic medical device
	Batch code		Consult instructions for use
	Date of manufacture		Keep dry
	Use-by date		Keep away from sunlight
	Manufacturer		Store at 2-8℃
	Do not re-use		Store at 2-30℃
	Authorized representative in the European		CE mark

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EC REP

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