PRL Rapid Quantitative Test

Catalog No.BT2207

INTENDED USE

The Biotime PRL (Prolactin) Rapid Quantitative Test is intended to quantify the concentration of PRL in human serum on Biotime FIA Analyzer by fluorescent immunoassay. The test is used as an aid detection of infertility.
-Fluorescence immunoassay
-Infertility
For in vitro diagnostic use only. For professional use only.

INTRODUCTION

PRL is a single chain protein, secreted by antepituitary basophil, which consist of 199 amino acids with molecular weight of 23kDa. PRL has the function of promoting proliferation of mammary gland and lactation. The level of PRL rises up during pregnancy, reaches its peak when delivery, then declines after lactication. Lactication with newborn will bring about an increase of the concentration. The concentration of PRL in blood rises up when there is pituitary tumor occurring, such as prolactin-producing tumor, acromegalia, primary hypothyroidism, cancer, hypothalamus tumor[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 PRL in the sample and the mouse anti-PRL 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 PRL 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 PRL in human serum.
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 PRL in human serum.

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 one-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 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. It may cause damages to the instrument.

MATERIAL

Material Provided
1. Test cartridge 25 tests/kit
2. Detection 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 (5~50μL and 10~100μL size)
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 shall be used within 30 minutes after opening the pouch.

SPECIMEN COLLECTION AND PREPARATION

1. The test can be performed with serum specimen.
2. The specimen collection container should be 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 must be recovered to the room temperature before tests.
4. Separate the serum from blood as soon as possible to avoid hemolysis.

TEST PROCEDURE

Please refer to the 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 with a transfer pipette and add it to 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 20 minutes.
NOTE: Please refer to the operation manual of a specific model of the analyzer for details.

REFERENCE INTERVAL

Normal Reference Value
Mature male: 86.30-425.72μIU/mL
Mature female: 72.55-600.40μIU/mL
Note: Individual reference range is suggested to be established for each laboratory.

LIMITATIONS OF PROCEDURE

1. The test sample should be serum.
2. Human anti-mouse antibody (HAMA) may be present 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, include the technology, operational error andother sample factors.

PERFORMANCE CHARACTERISTICS

Accuracy
Test cartridges from the same lot were tested with PRL control of three different levels of concentration, mean and Bias% were calculated, Bias% was within ±15%.
Assay Range: 1.0-4000.0μIU/mL
The Lowest Detection Limit: 1.0μIU/mL
Linearity
A serial concentration of PRL controls at 1.0-4000.0μIU/mL were tested, the Correlation Coefficient (R) is≥0.9900.
Precision
Intra-Lot Precision
Intra-lot precision was determined by testing of PRL 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 PRL reference materials using 30 test cartridges from 3 consecutive lots randomly (10 test cartridges from each lot). The C.V. is ≤ 20%.

SYMBOLS

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

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