

fPSA Rapid Quantitative Test

Catalog No.:BT2405

INTENDED USE

The Biotime fPSA Rapid Quantitative Test is intended to quantify the concentration of fPSA(Prostate Specific Antigen) in human serum on Biotime FIA Analyzer by fluorescent immunoassay. The test is used as an aid detection of prostate diseases including prostate cancer.

- Fluorescence immunoassay
- Prostate diseases

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

INTRODUCTION

Prostate-specific antigen (PSA), also known as gamma-seminoprotein or kallikrein-3 (KLK3), is a glycoprotein enzyme encoded in humans by the KLK3 gene. PSA is a member of the kallikrein-related peptidase family and is secreted by the epithelial cells of the prostate gland. PSA is present in small quantities(less than 4ng/mL) in the serum of men with healthy prostates, but is often elevated in the presence of prostate cancer or other prostate disorders^[1].

Most PSA in the blood is bound to serum proteins. A small amount is not protein bound and is called 'free PSA'. In men with prostate cancer the ratio of free (unbound) PSA to total PSA is decreased. The risk of cancer increases if the free to total ratio is less than 25%. (See graph at right.) The lower the ratio is, the greater the probability of prostate cancer. The FDA approved the use of %fPSA for screening in men with PSA's of 4-10ng/mL. The test is also included in professional guidelines on early detection of PCa from the National Comprehensive Cancer Network (NCCN) and European Association of Urology (EAU). The NCCN suggests %fPSA in men with no prior biopsy and PSA >3ng/mL, or prior negative biopsy with continued suspicion of cancer. The EAU recommends its use in men with PSA 2-10ng/mL prior to prostate biopsy^[2,3].

PRINCIPLE

This test kit is based on fluorescent lateral flow immunoassay. While the sample and the buffer is mixed and applied into the test cartridge, the fPSA in the sample and the mouse anti-fPSA 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 fPSA specific monoclonal antibodies). The intermediate complex will be captured by T-line to form final sandwich-like reaction complex. Thus the fluorescent signal on detection line is positively correlated with the concentration of fPSA in human serum.

The fluorescent signal from microspheres of T line will be detected and calculated according to the calibration curve (in SD card provided with the reagent) to represent the concentration of fPSA 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 1copy/kit

Material Required But Not Provided

1. Biotime FIA Analyzer
2. Transfer Pipette Set (range 5-50µL and 10-100µL size)
3. Specimen collection containers
4. Timer

STORAGE AND STABILITY

1. Store the detection buffer at 2-30°C, the shelf life is 24 months.
2. Store the test cartridge at 2-30°C, 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 specimen collection container shall be pro-coagulant tube for serum.
2. Sample collection: the venipuncture for blood collection method referring to the National

Clinical Laboratory Procedures, if the sample can't be detected timely, it can be stored in refrigerator at 2-8°C for 7 days, or at -20°C for 6months. Samples must be recovered to the room temperature before tests.

3. Separate the serum from blood as soon as possible to avoid hemolysis.

TEST PROCEDURE

Refer to Biotime FIA Analyzer Operation Manual for the complete instructions on use of the Test. The test should be operated at room temperature (~25°C) .

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.

Step 5: Testing

Ensure that there are no air bubbles. Immediately insert the test cartridge into analyzer and incubate for 15 minutes.

NOTE: Please refer to the operation manual of a specific model of the analyzer for details.

REFERENCE INTERVAL

Normal Reference Value: <1.0ng/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 and other sample factors.

PERFORMANCE CHARACTERISTICS

Accuracy

Test cartridges from same lot were tested with fPSA control of three different levels of concentration, mean and Bias% are calculated, Bias% is within ±15%.

Assay Range: 0.2-30.0ng/mL

The Lowest Detection Limit: 0.2ng/mL.

Linearity

A serial concentration of fPSA controls at 0.5-30.0ng/mL were tested, the Correlation Coefficient (R) is ≥0.9900.

Precision

Intra-Lot Precision

Within-run precision has been determined by using 10 replicates from same lot to test with fPSA control. The C.V. is ≤ 15.0%.

Inter-Lot Precision

Between-run precision has been determined by using 30 replicates from random 3 continuous lots to test with fPSA control. The C.V. is ≤20.0%.

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		Caution
	Do not re-use		Temperature limit is between at 2-30°C
	Do not use if package is damaged		Contains sufficient for <n> tests

BIBLIOGRAPHY OF SUGGESTED READING

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