tPSA Rapid Quantitative Test

Catalog No.: BT2404

INTENDED USE

The Biotime tPSA Rapid Quantitative Test is intended to quantify the concentration of tPSA(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.However, prostate cancer can also be present in the complete absence of an elevated PSA level, in which case the test result would be a false negative.PSA is not a unique indicator of prostate cancer, but may also detect prostatitis or benign prostatic hyperplasia.PSA levels can be also increased by prostatitis, irritation, benign prostatic hyperplasia (BPH), and recent ejaculation, producing a false positive result [1~4].
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 [5].

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 PSA in the sample and the mouse anti-PSA 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 PSA 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 tPSA 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 tPSA 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 (range 5~50μL and 10~100μL size)
3. Specimen collection containers
4. Timer

STORAGE AND STABILITY

1. Store the detection buffer at 2-30℃, 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 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℃ for 7 days，or at -20℃ 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℃）.
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：<4.0ng/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 [6,7].
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 tPSA control of three different levels of concentration, mean and Bias% are calculated, Bias% is within ±15%.
Assay Range: 0.5-200.0ng/mL
The Lowest Detection Limit: 0.5ng/mL
Linearity
A serial concentration of tPSA controls at 0.5-200.0ng/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 tPSA 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 tPSA control.The C.V. is ≤20.0%.

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

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