Finecare™ PSA (Prostate Specific Antigen) Rapid Quantitative Test

Catalog No. W209

INTENDED USE

The Finecare™ PSA (Prostate Specific Antigen) Rapid Quantitative Test along with Finecare™ FIA Meter is intended for vitro quantitative determination of Prostate Specific Antigen(PSA) in human serum.
-Fluorescence immunoassay
-Diagnosis of prostatic cancer

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

SUMMARY

Human prostate-specific antigen (PSA) is a serine protease, a single-chain glycoprotein with a molecular weight of approximately 34,000 daltons containing 7% carbohydrate by weight. PSA is immunologically specific for prostatic tissue. Elevated serum PSA concentrations have been reported in patients with prostate cancer, benign prostatic hypertrophy, or inflammatory conditions of other adjacent genitourinary tissues, but not in apparently healthy men, men with non-prostatic carcinoma, apparently healthy women, or women with cancer. Therefore, measurement of serum PSA concentrations can be an important tool in monitoring patients with prostate cancer and in determining the potential and actual effectiveness of surgery or other therapies.

Normal reference values: < 4ng/mL
Notice: Individual reference range is suggested to be established for each laboratory.

PRINCIPLE

The Finecare™ PSA Rapid Quantitative Test is based on fluorescence immunoassay technology. The Finecare™ PSA Rapid Quantitative Test uses a sandwich immunodetection method, when sample is added to the sample well of the test cartridge, the fluorescence-labeled detector PSA antibody on the membrane binds to PSA 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 PSA are captured to PSA antibody that has been immobilized on test strip. Thus the more PSA antigen is in blood specimen, the more complexes are accumulated on test strip. Signal intensity of fluorescence of detector antibody reflects amount of PSA captured and Finecare™ FIA Meter shows PSA concentrations in blood specimen. The default results unit of Finecare™ PSA Rapid Quantitative Test is displayed as XXX ng/mL from Finecare™ FIA Meter. The working range and the detection limit of the PSA Test system are 2～100 ng/mL and 2ng/mL.

PRECAUTIONS

1. This kit is for in vitro diagnostic use only.
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 with ID Chip # that is inserted onto the equipment.
5. The Finecare™ PSA 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 normal.
8. Use separate clean pipette tips and detector buffer vials for different specimens.
9. Blood specimens, used Test Cartridges, pipette tips and detector buffer vials should be handed and disposaled 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 Transfer Pipette Set (100μL size)
2. Specimen Collection Containers
3. Alcohol Pads
4. Centrifuge (for serum only)
5. Timer

STORAGE AND STABILITY

1. Store the detector buffer at 4～30℃. The buffer is stable up to 24 months.
2. Store Finecare™ PSA Rapid Quantitative Test Cartridge at 4～30℃, shelf life is up to 24 months.
3. Test cartridge should be used within 1 hour after opening the pack.

SPECIMEN COLLECTION AND PREPARATION

The test can be performed with only serum.

For Serum:
1. Separate the serum from blood as soon as possible to avoid hemolysis.
2. 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
Check/insert ID Chip into the equipment.
Take out one tube of Buffer from refrigerator and balance it at room temperature for a couple of minutes
Step2: Sampling
Draw 75μL of serum 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 75μL 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, 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”. 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. 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.

QUALITY CONTROL

Each Finecare™ PSA Rapid Quantitative 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 serum specimen only.
2. The results of Finecare™ PSA Rapid Quantitative Test should be evaluated with all clinical and laboratory data available. If PSA test results do not agree

with the clinical evaluation, additional tests should be performed.

3. The false positive results may come from cross-reactions with some similar antibodies in blood; and similar epitopes from non-specific components in blood capturing fluorescent labeled antibodies.
4. The false negative results may from some unknown substance blocking epitope adhering antibodies, unstable or degenerated PSA that cannot be identified due to prolonged time and temperature and storage condition of sample and reagent.
5. Other factors may interfere with Finecare™ PSA 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 PSA control of 5ng/mL, 10ng/mL and 20ng/mL, mean and Bias% were calculated, Bias% was within 15%.

Assay Range and Detection Limit

- **Assay Range**: 2~100 ng/ml
- **Detection Limit:** 2ng/mL

Linearity

A serial concentration of PSA controls at 5ng/ml, 10ng/ml, 15ng/ml, 20.0ng/ml, 30.0ng/ml, 40.0ng/ml were tested, the Correlation Coefficient (R) is ≥ 0.99

Precision

Intra-Run

Within-run precision has been determined by using 10 replicates from same batch to test with 5.0ng/ml PSA control. C.V. is ≤ 15%.

Inter-Run

Between-run precision has been determined by using 3 replicates from random 3 continuous batches to test with 5.0ng/mL PSA control. C.V. is ≤ 15%.

BIBLIOGRAPHY OF SUGGESTED READING

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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℃				