Finecare™

PSA Rapid Quantitative Test

Catalog No. W209

INTENDED USE

The Finecare™ PSA Rapid Quantitative Test is a fluorescence immunoassay used along with Finecare™ FIA System (Model No.: FS-112/FS-113/FS-205) for quantitative determination of Prostate Specific Antigen (PSA) in human whole blood, serum or plasma.
The test is used as an aid in diagnosis of prostatic cancer.

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

SUMMARY

Prostate-specific antigen (PSA) is a single-chain glycoprotein with molecular weight of 34 kilodaltons. As a serine protease with chymotrypsin-like activity, PSA belongs to the kallikrein family. In blood, PSA exists as a free or complex form with protease inhibitors such as α-1-antichymotrypsin (ACT). Total PSA represents the sum of both free and complex forms.PSA is uniquely associated with prostate tissues from normal, inflamed or cancerous stages. Elevated PSA in blood is found in patients with prostate cancer, benign prostatic hypertrophy, or inflammatory tissues. Studies on a variety of PSA methods have shown that PSA can be useful as an indicator for the diagnosis and management of prostate cancer.
PSA has been found in normal, benign hyperplastic, and malignant prostatic tissue, in metastatic prostatic carcinoma, and also in prostatic fluid as well as in seminal fluid.PSA is not found in any other tissue in men, and it is not produced by cancers originating in the lung, colon, rectum, stomach, pancreas or thyroid.Though increased concentrations of PSA are found in the serum of patients with benign prostate hyperplasia (BPH), prostatitis and prostate infections and inflammation, they are also found in patients with cancer of the prostate.PSA measurement is an essential tool in assessing the status of disease in patients with prostate cancer when serial samples are measured over time. The clinical value realized by monitoring PSA concentrations in patients with prostate cancer regardless of the treatment regimen is well known. Since the mid-1980's, there has been a growing body of literature concerning the utility of Prostate Specific Antigen (PSA) for both the monitoring and detection of prostate cancer (CaP).

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 into the sample well of the Test Cartridge, the fluorescence-labeled detector PSA antibodies on the sample pad bind to PSA antigens in blood specimen and they form immune complexes. As the complexes migrate on the nitrocellulose matrix of test strip by capillary action, the complexes of detector antibodies and PSA are captured to PSA antibodies that have been immobilized on test strip. Thus the more PSA antigens in blood specimen, the more complexes accumulated on test strip. Signal intensity of fluorescence of detector antibodies reflect the amount of captured PSA.

PRECAUTIONS

1. This kit is for *in vitro* diagnostic use only.
2. Carefully follow the instructions and procedures described in this insert.
3. Lot number of all the test components (Test Cartridge, ID Chip and Detection Buffer) must match with each other.
4. Do not interchange the test components from different lots or use the test components beyond the expiration date printed on package.
5. The Finecare™ PSA Rapid Quantitative Test kit is only operated in Finecare™ FIA System. Tests should be applied by professionally trained staff working in certified laboratories and clinics at which the sample(s) is taken by qualified medical personnel.
6. The Test Cartridge should remain in its original sealed pouch until use. Do not use the Test Cartridge if the pouch is damaged or already opened.
7. A Detection Buffer vial and Pipette Tip should be used for processing one sample only. Similarly a Test Cartridge should be used for testing one processed sample only. Both the Detection Buffer vial as well as the test cartridge should be discarded after single use.
8. The Test Cartridge and Finecare™ FIA System should be used away from vibration and/or magnetic field. During normal usage, the Test Cartridge may produce minor vibrations which should be regarded as normal.
9. Do not smoke, eat, or drink in the areas where specimens or test reagents are being handled.
10. Blood specimens, used Test Cartridges, Pipette Tips and Detection Buffer vials are potentially infectious. They should be handled carefully and disposed of by an appropriate method in accordance with relevant local regulations.
11. The Finecare™ PSA Rapid Quantitative Test should not be used as absolute evidence of diagnosis of prostatic cancer. The results should be interpreted by the physician along with clinical findings and other laboratory test results.
12. The test should be applied on a routine basis but not in emergency situations.

MATERIAL

Material Provided

Components of Finecare™ PSA Rapid Quantitative Test:

● Test Cartridge in a sealed pouch with desiccant	25
● ID Chip	1
● Detection Buffer	25
● Pipette Tip	25
● Leaflet with Instructions for Use	1

Material Required But Not Provided

- Finecare™ FIA System
- Transfer Pipette Set (100 µL size)
- Specimen Collection Containers
- Centrifuge (for serum specimen only)
- Timer

STORAGE AND STABILITY

1. Store the test kit at 4～30℃ up to the expiration date.
2. If removed from refrigerator, allow the test for 30 minutes to return to room temperature before testing.
3. Do not remove the device from the pouch until ready to use. The test cartridge should be used within 1 hour once opened.

SPECIMEN COLLECTION AND PREPARATION

The test can be performed with either serum or plasma or whole blood.

For Whole Blood Collected by Venipuncture:

1. Following standard phlebotomy procedure, collect a venipuncture whole blood specimen using a blood collection tube with suitable anticoagulant (EDTA or heparin sodium).
2. Gently mix the specimen after collecting. It is recommended that specimens should be tested immediately.
3. If the specimens are not tested in 2 hours, they should be stored at 2℃~8℃ for up to 2 days.

For Serum and Plasma:

1. Following standard phlebotomy procedure, collect a venipuncture whole blood specimen using a blood collection tube. If collecting plasma use a blood collection tube containing suitable anticoagulant (EDTA).
2. Separate the serum/plasma from blood as soon as possible to avoid hemolysis.
3. 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 7 days. For long-term storage, specimens should be kept below -20℃.

Note: Frozen plasma or refrigerated whole blood or serum must be rapidly thawed to reach room temperature then mixed thoroughly before use.
No more than a single freeze/thaw cycle is recommended. Clotted or severely hemolytic specimens are not suitable for testing and shall be rejected. Another specimen should be obtained and tested.

TEST PROCEDURE

For complete information and operation procedures, please refer to Finecare™ FIA System Operation Manual. Test should be performed at room temperature.

Step 1: Preparation
Before testing, activate "use" in setting then save it.
Ensure that the lot number of the Test Cartridge matches ID Chip as well as the Detection Buffer. Insert ID Chip into Finecare™ FIA System.

Step 2: Sampling
Draw 75 µL of whole blood/serum/plasma with a transfer pipette and add it to the buffer tube.

Step 3: Mixing
Close the lid of Detection Buffer tube and mix the sample mixture thoroughly by shaking it about 10 times.

Step 4: Loading
Take 75 µL of sample mixture and load it into the sample well of the Test cartridge.

Step 5: Testing
There are two test modes for Finecare™ FIA System, Standard Test mode and Quick Test mode. Please refer to the Operation Manual of Finecare™ FIA System for details.

a) **For Standard Test mode:** Insert the Test Cartridge onto the Test Cartridge holder of Finecare™ FIA System right after adding sample mixture to the sample well. Press "**Test**" to start testing. (Apply to FS-112, FS-113 and FS-205)

b) **For Quick Test mode:** Set the timer and count down right after adding sample mixture into the sample well and leave it at room temperature for 15 minutes. Then insert the Test Cartridge onto the Test Cartridge holder of Finecare™ FIA System. Press "**Test**" to start testing. Finecare™ FIA System will start scanning the sample-loaded Test Cartridge immediately. (Apply to FS-112 and FS-113)

Results are displayed on main screen or be printed by press "**Print**".
Discard the used Test Cartridge according to local regulations and procedures after released from Finecare™ FIA System.

Traceability: Values of this product are linked to the WHO PSA standard (NIBSC code: 96/670) based on the respective instrument calibration traceability.

INTERPRETATION OF RESULTS

The Finecare™ FIA System calculates PSA test results automatically and displays the exact concentrations of PSA on the screen as form of XXX.X ng/mL. For further information, refer to the Operation Manual for the Finecare™ FIA System.

Concentration	Clinical Reference
＜4ng/mL	Normal Levels.
≥4ng/mL	Indicating the risk of prostate cancer.

Note: Recommend that each laboratory formulates its own Reference Range according to actual situation.

QUALITY CONTROL

Each Finecare™ PSA Rapid Quantitative Test contains internal control that satisfies routine 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 System. An invalid result from the internal control causes an error message on Finecare™ FIA System indicating that the test should be repeated.

LIMITATIONS OF PROCEDURE

1. This test has been developed for testing human whole blood, serum or plasma specimen only.
2. The results of Finecare™ PSA Rapid Quantitative Test should be evaluated with all clinical and laboratory data available.
3. The erroneous results include cross-reactions with some components of serum from individual to antibodies; and non-specific adhesion of some components in human blood that have similar epitopes to capture and detector antibodies. In the case of erroneous results, the most common factors are: non-responsiveness of antigen to the antibodies by that certain unknown components are masking its epitope, such that antigen cannot be seen by the antibodies; instability of PSA, resulting in degradation with time and, or temperature, such that they become no longer recognizable by antibodies; and degraded other test components. The effectiveness of the test is highly dependent on storage of kits and sample specimens at optimal conditions.
4. Plasma/whole blood using anticoagulants (e.g. heparin or citrate) other than EDTA(EDTA-Na2, EDTA-K2, EDTA-K3) has not been evaluated in Finecare™ PSA Rapid Quantitative Test and thus should not be used.
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

Three comparison studies in 2016 using 1016 human blood samples, demonstrated good correlation with a commercially available kit.

Comparison between the Finecare™ PSA Rapid Quantitative Test and the Boditech Med Inc PSA Test reagent for the 1016 clinical samples, the Correlation Coefficient is 0.970.

Assay Range and Detection Limit

- **Assay Range:** 2.0-100.0ng/mL
- **Detection Limit (Analytical Sensitivity):** ≤2.0ng/mL

Cross-Reactivity

The following substances do not interfere with the test results at the indicated concentrations:

Bilirubin	≤2 mg/dL
Triglyceride	≤5000 mg/dL
AFP	≤289 ng/mL
TPS	≤200 U/L
Cholesterol	≤1000 mg/dL
Haemoglobin	.≤15g/L

Linearity

A serial concentration of PSA samples at 0.006~105.22 ng/mL were each tested for three times, the Correlation Coefficient (R) is ≥ 0.99.

Precision

Intra-Lot Precision:
One batch is used to test 5ng/mL and 20ng/mL PSA specimen, test repeatedly for ten times; CV% should be within 15%.

Inter-Lot Precision:
Three batches are used to test 5ng/mL and 20ng/mL PSA specimen, test ten times for each batch; CV% should be within 20%.

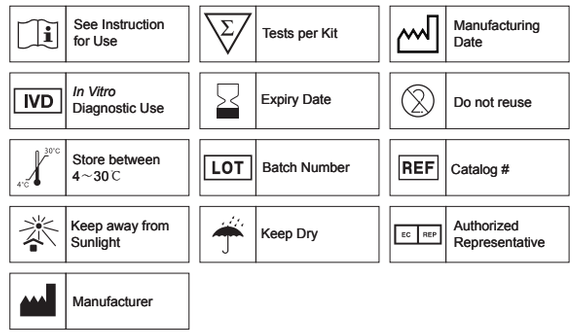
Hook Effect

No high dose hook effect was seen in samples with a PSA concentration as high as 1200ng/ml.

BIBLIOGRAPHY OF SUGGESTED READING

1. de Koning HJ, Liem MK, Baan CA, Boer R, Schröer FH, Alexander FE, Prostate cancer mortality reduction by screening: power and time frame with complete enrollment in the European Randomized Screening for Prostate Cancer (ERSPC) trial. International Journal Cancer, 2002; 98:268-73.
2. Wan-Ming Zhang, Patrik Finne, Jari Leinonen et al., Characterization and immunological determination of the complex between prostate-specific antigen and a2-macroglobulin, Clinical Chemistry, 1998, 44:12, 2471–2479.
3. David L. Woodrum et al., Analytical performance of the Tandem-R free PSA immunoassay measuring free prostate-specific antigen. Clinical Chemistry, 1997, 43:7, 1203–1208.
4. Yun Sik Kwak, M.D., Appropriate use of Prostate-Specific Antigen in Diagnosing Carcinoma of the Prostate. Journal Korean Geriatrics Society, 2009, Vol.13, Mar, pp. 12-17.
5. Chen Z, Prestigiacomo A, et al., Purification and characterization of prostate-specific antigen(PSA) complexed to alpha 1-antichymotrypsin: potential reference material for international standardization of PSA immunoassays, Clinical Chemistry, 1995, 41(9):1273-82.
6. Wang, M.C., et al, 1981, Prostatic Antigen: A New Potential Marker for Prostatic Cancer. Prostate 2:89.
7. Frankel, A.G., et al, 1982, Monoclonal Antibodies to a Human Prostate Antigen. Cancer Res. 42:3714
8. Papsidero, L.D., et al, 1980, A Prostate Antigen in Sera of Prostatic Cancer Patients. Cancer Res. 40:2428.
9. Kuriyama, M., et al, 1980, Quantitation of Prostate-Specific Antigen in Serum by a Sensitive Enzyme Immunoassay. Cancer Res. 40:4658.
10. Killian, C.S., 1985, Prognostic Importance of Prostate-Specific Antigen for Monitoring Patients with Stages B2 to D1 Prostate Cancer. Cancer Res. 45:886.
11. Kuriyama, M., et al, 1982, Multiple Marker Evaluation in Human Prostate Cancer with the Use of Tissue-Specific Antigens. J. Nat. Canc. 68:99.
12. Nahm MH and Goffman JW. Heteroantibody: Phantom of the Immunoassay. Clinical Chemistry, 1990, 36:829.
13. Boscato LM., Stuart MC., Heterophilic Antibodies: A Problem for All Immunoassay Compared. Clinical Chemistry, 1988, 33:1916-20.

INDEX OF SYMBOLS



Guangzhou Wondfo Biotech Co., Ltd.
No.8 Lizhishan Road, Science City, Luogang District,
510663, Guangzhou, P.R. China

EC REP
Qarad b.v.b.a.
Cipalstraat 3
0123 B-2440 Geel, Belgium

Rev. A2 Rel.: 2018/02/27

Wondfo® 万孚	物料编码及项目名称：1.5.2.3.05021 说明书 新（飞测PSA定量检测试剂）英文		
	尺寸规格：340*125mm	颜色：黑色	设计师：许广添
	材质：80克铜版纸	申请人：周梦琳	设计时间： 2018.03.05