Finecare™

FPSA Rapid Quantitative Test

Catalog No. W230

INTENDED USE

The Finecare™ FPSA 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 Free Prostate Specific Antigen (FPSA) 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 secreted by the prostate gland epithelial cells of a serine protease. Total PSA (TPSA) which can be immune detected, includes free PSA and PSA-ACT complex. In the male serum, PSA screening can be used as one of the diagnostic index of early prostate cancer (PCa). PSA levels associated with prostate disease, including prostatitis, benign prostatic hyperplasia (BPH) and prostate cancer (PCa). The patients with BPH have higher percentage of free PSA than the men with PCa significantly. FPSA/TPSA ratio can be used in the differential diagnosis between prostate cancer and benign prostatic hyperplasia.
The determination of FPSA levels is recognized as an important measurement in the assessment of prostate disease.

PRINCIPLE

The Finecare™ FPSA Rapid Quantitative Test is based on fluorescence immunoassay technology. The Finecare™ FPSA Rapid Quantitative Test uses a sandwich immunodetection method. When sample is added into the sample well of the Test Cartridge, the fluorescence-labeled detector FPSA antibodies on the sample pad bind to FPSA 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 FPSA are captured to FPSA antibodies that have been immobilized on test strip. Thus the more FPSA antigens in blood specimen, the more complexes accumulated on test strip. Signal intensity of fluorescence of detector antibodies reflect the amount of captured FPSA.

PRECAUTIONS

1. 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™ FPSA 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™ FPSA 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™ FPSA 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/plasma specimen only)
- Timer

STORAGE AND STABILITY

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

SPECIMEN COLLECTION AND PREPARATION

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

For Whole Blood Collected by Venipuncture:

1. According to standard phlebotomy procedure, collect a venipuncture whole blood specimen with a blood collection tube which contains suitable anticoagulant (EDTA, Heparin and Sodium Citrate).
2. It is recommended that specimens should be tested immediately. Do not leave the specimens at room temperature for prolonged period. If the specimens are not tested immediately, they should be kept at 2℃~8℃.
3. It is not suitable to test the whole blood specimen which have been kept at 2℃~8℃ for more than 2 days.

For Plasma or Serum:

1. According to standard phlebotomy procedure, collect a venipuncture whole blood specimen. If you need to collect plasma, please use a blood collection tube which contains suitable anticoagulant (EDTA, Heparin and Sodium Citrate).
2. Separate the serum/plasma from blood as soon as possible to avoid hemolysis.
3. Test should be performed immediately after specimen collection. Do not leave the specimens at room temperature for prolonged period. Specimens should be kept at 2℃~8℃ for up to 7 days. For long time storage, specimens should be kept below -20℃.

Note: Bring specimens to room temperature before testing. Frozen specimens must be completely thawed and mixed well prior to testing. Specimens should not be frozen and thawed repeatedly. Only clear, non-hemolytic specimens can be used.

TEST PROCEDURE

For complete information and operating 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 serum or plasma or whole blood specimen with a transfer pipette and add into the Detection 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

Pipette 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.

INTERPRETATION OF RESULTS

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

Normal Reference Value: < 1 ng/mL

Note: Recommend that each laboratory formulates its own reference range according to actual situation.

QUALITY CONTROL

Each Finecare™ FPSA Rapid Quantitative Test Cartridge contains internal control that satisfies routine quality control requirements. This internal control is performed each time when 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 serum.
2. The test procedure, precautions and interpretations of results for this test must be followed when testing.
3. The results of Finecare™ FPSA Rapid Quantitative Test should be evaluated with all available clinical and laboratory data.
4. The false positive 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 false negative 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 FPSA antigen, 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.
5. Other factors may interfere with Finecare™ FPSA 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

A comparative study is tested for 277 clinical samples in using Finecare™ FPSA Rapid Quantitative Test and the Roche FPSA reagent kit.
The Correlation Coefficient (R^2) is 0.971.

Assay Range and Detection Limit

- **Assay Range:** 0.2~30 ng/mL
- **Detection Limit (Analytical Sensitivity):** 0.2 ng/mL

Cross-Reactivity

The FPSA test results do not be interfered with the substance at the following concentrations: CEA at 500ng/L, AFP at 400 ng/mL, PSA-ACT at 200 ng/mL.

The FPSA test results do not be interfered with the substance at the following concentrations: cholesterol at 1000 mg/dL, bilirubin at 2 mg/dL, triglycerides at 5000 mg/dL and hemoglobin at 1.0 g/dL.

Linearity

Five concentrations of FPSA controls from 0.2~30 ng/mL were each tested for three times with one batch of tests, the Correlation Coefficient (R) is ≥ 0.9900.

Precision

Intra-Lot Precision:

Determined by using 10 Test Cartridges in the same batch to test with FPSA control. C.V. is ≤15%.

Inter-Lot Precision:

Determined by using 3 Test Cartridges in 3 random and continuous batches to test with FPSA control. C.V. is ≤20%.

Hook Effect

No high dose hook effect was seen in samples with a FPSA concentration as high as 100 ng/mL.

BIBLIOGRAPHY OF SUGGESTED READING

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4. Partin AW, Oesterling JE. The Clinical Usefulness of Prostate Specific Antigen: Update 1994 J Urol 1994; 152:1358-68.
5. Stenman U-H, Leinonen J, Alfthan H, et al.A Complex Between Prostate-Specific Antigen and α1-Antichymotrypsin is the Major Form of Prostate-Specific Antigen in Serum of Patients with Prostatic Cancer: Assay of the Complex Improves Clinical Sensitivity for Cancer.Cancer Res 1991; 51:222-6.
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8. Luderer AA, Chen Y-T, Soriano TF, et al.Measurement of the Proportion of Free to Total Prostate-Specific Antigen Improves Diagnostic Performance of Prostate-Specific Antigen in the Diagnostic Gray Zone of Total Prostate-Specific Antigen. Urology 1995; 46: 187-94.
9. Catalona WJ, Smith DS, Wolfert RL, et al. Evaluation of Percentage of Free Serum Prostate-Specific Antigen to Improve Specificity of Prostate Cancer Screening. JAMA 1995; 274:1214-20.
10. Partin AW, Oesterling JE, Editor. The Clinical Usefulness of Percent Free Prostste-Specific Antigen. Urology (Suppl.No.6A) 1996; **48:1-87.**

INDEX OF SYMBOLS

	See Instruction for Use		Tests per Kit		Manufacturing Date
IVD	*In Vitro* Diagnostic Use		Expiry Date		Do not reuse
	Store between 4～30℃	LOT	Batch Number	REF	Catalog #
	Keep away from Sunlight		Keep Dry	EC REP	Authorized Representative
	Manufacturer				

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

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

Rev. A1 Rel.: 2018/01/11

Wondfo 万孚	物料编码及项目名称：1.5.2.3.04910 说明书 新 （ 飞测fPSA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： 2018.02.01