Free PSA FIA Rapid Test Device

(Serum/Plasma)

Catalogue Number: FI2-FPSA-001

A rapid test for detecting free Prostate Specific Antigen (FPSA) in serum or plasma with the use of the Biopanda Fluorescence Immunoassay Device (BR-FIA-2000).

For professional in vitro diagnostic use only.

INTENDED USE

The Biopanda Free PSA FIA Rapid Test Device is based on fluorescence immunoassay for the quantitative determination of free PSA in serum or plasma.

BACKGROUND

Prostate Specific Antigen (PSA) is a protein that the body produces in the prostate gland and parts of the urinary system. There are different forms of PSA, including total and free PSA. They can either bind to another protein or float freely.[1] If a man's PSA level is between 4-10 ng/mL doctors sometimes call it a borderline result. This is because, although the PSA is higher than average, most men who have a PSA of between 4 and 10 won't have prostate cancer. This is especially the case for men whose prostate feels normal on digital rectal examination (DRE). The free PSA test is a test doctors sometimes use to help them decide how likely it is that a man has prostate cancer when the total PSA result is borderline.

The percentage of free PSA that makes up the total PSA is not the same for all men. It is believed that the higher the percentage of free PSA a man has, the less likely it is that he has prostate cancer. Some studies have shown that if the free PSA makes up more than a 25% of a man's total PSA he is at low risk of having prostate cancer. And, that men with a lower percentage of free PSA are at higher risk of having prostate cancer.[2,3,4,5]

TEST PRINCIPLE

The Biopanda Free PSA FIA Rapid Test Device detects free PSA based on fluorescence immunoassay. The specimen moves through the strip from the specimen pad to absorbent pad. If the specimen contains free PSA, it attaches to the fluorescent microspheres-conjugated anti-FPSA antibodies. Then the complex will be captured by the capture antibody coated on the nitrocellulose membrane. The concentration of Free PSA in the specimen correlates with the fluorescence signal intensity captured on the T line. According to the fluorescence intensity of the test and product standard curve, the concentration of Free PSA in the specimen can be calculated by the Biopanda Fluorescence Immunoassay Device to show Free PSA concentration in specimen.

REAGENTS

The test kit includes anti-FPSA monoclonal antibody coated fluorophores and anti-PSA antibody coated on the membrane.

PRECAUTIONS

1. For professional *in vitro* diagnostic use only.
2. Do not use after the expiration date indicated on the package. Do not use the test if the foil pouch is damaged. Do not reuse.
3. Avoid cross-contamination of specimens by using a new specimen collection container for each specimen obtained.
4. Do not eat, drink or smoke in the area where the specimens and tests are handled. Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout the procedure and follow standard procedures for proper disposal of specimens. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed.
5. Do not interchange or mix reagents from different lots.
6. Humidity and temperature can adversely affect results.
7. Used testing materials should be discarded in accordance with local regulations.
8. Read the entire procedure carefully prior to any testing.
9. The Biopanda Free PSA FIA Rapid Test Device should only be used with the Biopanda Fluorescence Immunoassay Device (BR-FIA-2000) by approved medical professionals.

STORAGE AND STABILITY

1. The kit should be stored at 4-30°C until the expiry date printed on the sealed pouch.
2. The test must remain in the sealed pouch until use.
3. Do not freeze.
4. Care should be taken to protect the components of the kit from contamination. Do not use if there is evidence of microbial contamination or precipitation. Biological contamination of dispensing equipment, containers or reagents can lead to false results.

KIT CONTENTS

- 25 x Foil wrapped Free PSA Rapid Test Devices
- 25 x Specimen collection tubes with dilution buffer
- 1 x ID card (FPSA)
- 1 x Package Insert

REQUIRED BUT NOT PROVIDED

- Timer
- Centrifuge
- Pipette
- Biopanda Fluorescence Immunoassay Device (BR-FIA-2000)

SPECIMEN COLLECTION AND PREPARATION

For Venipuncture Specimens

1. Collect the specimen according to standard procedures.
2. Separate serum/plasma from whole blood as soon as possible to avoid haemolysis. Only clear, non-haemolysed specimens should be used.
3. Do not leave specimens at room temperature for prolonged periods. Specimens may be stored at room temperature for up to 9 hours. Serum and plasma specimens can be stored at 2-8°C for up to 3 days, but for long term storage should be kept below -20°C. Whole blood collected by venipuncture can be stored at 2-8°C for up to 2 days. Do not freeze whole blood specimens.
4. Bring specimens to room temperature prior to testing. Frozen specimens must be completely thawed and mixed well prior to testing. Avoid repeat freeze-thaw cycles.
5. EDTA K2, Citrate Sodium, and Potassium Oxalate can be used as the anticoagulant for collecting blood specimens.

DIRECTIONS FOR USE

Refer to the Biopanda Fluorescence Immunoassay Device Operation Manual for the complete instructions on use of the test. The test should be conducted at room temperature. Cold buffer solution or moisture condensation on the membrane can lead to invalid test results.

Allow the test, specimen, buffer and/or controls to reach room temperature (15-30°C) prior to testing.

1. Turn on the Analyser. Then according to the user requirement, select "Standard test" or "Quick test" mode.
2. Take out the ID card and insert it into the Analyser port.
3. Remove the test device from the sealed foil pouch and start testing as soon as possible.
4. Follow the appropriate steps below for the chosen specimen type:
   - **4.1 <u>For venipuncture serum/plasma specimens:</u>**
     - i. Pipette **75 µl of serum/plasma** into the buffer tube.
     - ii. Close the tube cap and shake the tube for approximately **10 seconds** to mix the specimen and dilution buffer well.
     - iii. Let the diluted specimen homogenise for approximately 1 minute. Diluted specimens should be used as soon as possible.
     - iv. **Pipette 75 µl of diluted specimen** into the specimen well (S) of the test Device. Start the timer at the same time.
5. Test results should be read at **15 minutes** with the use of the Biopanda Fluorescence Immunoassay Analyser.

Note: The Biopanda Fluorescence Immunoassay Device has two possible test modes: Standard Test mode and Quick Test mode. Please refer to the manual for more details.

Quick test mode: Insert the test device into the analyser 15 minutes after specimen application and select "New Test". The analyser will display the test result after a few seconds.

Standard test mode: Insert the test device into the analyser immediately after specimen application and select "New Test". The analyser will automatically start a timer for 15 minutes, after which the analyser will display the test result.

INTERPRETATION OF RESULTS

Test results are calculated by the Biopanda Fluorescence Immunoassay Device (BR-FIA-2000) and displayed on the analyser screen. For additional information, please refer to the operational manual.

QUALITY CONTROL

Each test contains an internal control that satisfies routine quality control requirements. This internal control is performed each time a patient specimen is tested. This control indicates that the test device was inserted and read properly by the Biopanda Fluorescence Immunoassay Device. An invalid result from the internal control causes an error message on the Biopanda Fluorescence Immunoassay Device indicating that the test should be repeated. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control failure. Review the procedure and repeat the test with a new test. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

EXPECTED RESULTS

FPSA/TPSA Ratio	Percentage probability of Prostate Cancer (%)		
	50-59 years	60-69 years	≥70 years
≤0.10	49.2	57.5	64.5
0.11-0.18	26.9	33.9	40.8
0.19-0.25	18.3	23.9	29.7
>0.25	9.1	12.2	15.8

Multiple factors such as population, age, specificity of test method may affect interpretation of FPSA and TPSA values. The ranges should be used as guidelines only. Each laboratory should establish its own reference values.

PERFORMANCE CHARACTERISTICS

1. **Method comparison**

For 105 specimens, the test results of FPSA test cassettes were compared with a commercial CLIA free PSA test kits and the correlation coefficient (R2) is 0.9882.

2. **Accuracy**

The test deviation is ≤ ±15%.

3. **Assay Range**

Assay Range is 0.1-30 ng/mL.

4. **Precision**

Intra-lot precision

Within-run precision has been determined by using 10 replicates of 2 different concentration FPSA control. C.V. is ≤ 15%.

Inter-lot precision

Between-run precision has been determined by using 10 replicates for each of three lots using 2 different concentrations FPSA control C.V. is ≤15%.

LIMITATIONS OF THE TEST

1. The Biopanda Free PSA FIA Rapid Test Device is for professional *in vitro* diagnostic use, and should only be used for the quantitative detection of free PSA.
2. The test will only indicate the presence of free PSA antigen in the specimen and should not be used as the sole criterion for the diagnosis of prostate cancer.
3. A significant numbers of patients with BPH (more than 15%) and less than 1% of healthy individuals have elevated PSA. Even if the test results are positive, further clinical evaluation should be considered with other clinical information available to the physician.
4. Free PSA levels may be unreliable in patients who receive hormone therapy or prostate gland manipulation.
5. As with all diagnostic tests, a confirmed diagnosis should only be made by a physician after all clinical and laboratory findings have been evaluated.
6. The results of the Biopanda Free PSA FIA Rapid Tests are based on measuring the levels of free PSA in a specimen. It should not be used as the sole criterion for treatment decisions. If the result is positive, other clinical findings and alternative test methods are recommended to reach proper medical treatments.

REFERENCES

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2. Catalona WJ, Smith DS, Wolfert RL, Wang TJ, Rittenhouse HG, Ratliff TL, Nadler RB. Evaluation of percentage of free serum prostate-specific antigen to improve specificity of prostate cancer screening. JAMA 1995; 274: 1214–1220.
3. Partin AW, Catalona WJ, Southwick PC, Subong ENP, Gasior GH, Chan DW. Analysis of percent free prostate-specific antigen (PSA) for prostate cancer detection: Influence of total PSA, prostate volume, and age. Urology 1996; 48 (Suppl): 55–61.
4. Van Cangh PJ, De Nayer P, Sauvage P, Tombal B, Elsen M, Lorge F, Opsomer R, Wese F. Free to total prostate-specific antigen (PSA) ratio is superior to total PSA in differentiating benign prostate hypertrophy from prostate cancer. Prostate 1996; 7 (Suppl): 30–34.
5. Woodrum DL, Brawer MK, Partin AW, Catalona WJ, Southwick PC. Interpretation of free prostate specific antigen clinical research studies for the detection of prostate cancer. J Urol 1998; 159: 5–12.

INDEX OF SYMBOLS

	Manufacturer	Σ	Tests per kit	2	Do not reuse test
IVD	*In vitro* diagnostic medical device		Expiration date	REF	Catalogue number
	Store between 4-30°C	LOT	Lot Number		Consult instructions for use
	Do not use if package is damaged				

Thank you for purchasing Biopanda's Free PSA FIA Rapid Test Device. Please read this manual carefully before operating to ensure proper use.

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