PSA FIA Rapid Test

(Serum/Plasma)

FIA-PSA-001

A rapid test for detecting Prostate Specific Antigen (PSA) in serum or plasma with the use of the Biopanda Fluorescence Immunoassay Analyser.
For professional in vitro diagnostic use only.

INTENDED USE

The Biopanda PSA FIA Rapid Test is based on Fluorescence Immunoassay for the quantitative determination of PSA in serum or plasma.

SUMMARY

Prostate specific antigen (PSA) is produced by prostate glandular and endothelial cells. It is a single chain glycoprotein with a molecular weight of approximate 34 kDa.[1] PSA exists in three major forms circulating in the serum. These forms are free PSA, PSA bound to α1 – Antichymotrypsin (PSA-ACT) and PSA complexed with α2–macroglobulin (PSA-MG).[2]
PSA has been detected in various tissues of the male urogenital system but only prostate glandular and endothelial cells secrete it. The PSA level in serum of healthy men is between 0.1 ng/mL and 2.6 ng/mL. It can be elevated in malignant conditions such as prostate cancer, and in benign condition such as benign prostatic hyperplasia and prostatitis. A PSA level of 4 to 10ng/ml is considered to be in the "gray-zone" and levels above 10ng/ml are highly indicative of cancer.[3] Patients with PSA values between 4-10ng/ml should undergo further analysis of the prostate by biopsy.
The prostate specific antigen test is the most valuable tool available for the diagnosis of early prostate cancer. Many studies have confirmed that the presence of PSA is the most useful and meaningful tumor marker known for prostate cancer and prostate infection of Benign Prostatic Hyperplasia (BPH).[4]

PRINCIPLE

The PSA FIA Rapid Test Cassette detects PSA based on Fluorescence Immunoassay. The sample moves through the strip from sample pad to absorbent pad. If the specimen contains PSA, it attaches to the fluorescent microspheres-conjugated anti-PSA antibodies. Then the complex will be captured by the capture antibody coated on the nitrocellulose membrane. The concentration of PSA in the sample 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 PSA in the sample can be calculated by the Biopanda Fluorescence Immunoassay Analyser to show PSA concentration in specimen.

REAGENTS

The test kit includes anti-PSA 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 PSA FIA Rapid Test should only be used with the Biopanda Fluorescence Immunoassay Analyser 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 COMPONENTS

- 10 x foil wrapped PSA test cassettes
- 10 x Specimen collection tubes with dilution buffer
- 1 x ID card (PSA)
- Package Insert

MATERIALS REQUIRED BUT NOT PROVIDED

- Timer
- Centrifuge
- Pipette
- Biopanda Fluorescence Immunoassay Analyser

SPECIMEN COLLECTION AND PREPARATION

PREPARATION

1. Before performing the test, please make sure that all components are brought to room temperature (15-30°C). Cold buffer solution or moisture condensation on the membrane can lead to invalid test results.
2. Take a tube with buffer solution out of the kit. Document patients name or ID on it. Open the screw cap.

BLOOD SAMPLE TAKING

1. Collect the specimen according to standard procedures.
2. Do not leave specimens at room temperature for prolonged periods. Serum and plasma specimens may be stored at 2-8 °C for up to 3 days, for long term storage, specimens should be kept below -20 °C.
3. Bring specimens to room temperature prior to testing. Frozen specimens must be completely thawed and mixed well prior to testing. Avoid repeated freezing and thawing of specimens.
4. EDTA and Heparin sodium, can be used as the anticoagulant for collecting the specimen.

SAMPLE DILUTION / SAMPLE STABILITY

1. Transfer **20 µL of serum or plasma** to the buffer tube with a micro pipette.
2. Close the tube and shake the sample by hand vigorously for approximately **10 seconds** to mix the sample and dilution buffer.
3. Let the diluted sample homogenize for approximately 1 minute.
4. The diluted sample can then be used immediately or stored for up to 8 hours.

DIRECTIONS FOR USE

Refer to the Biopanda Fluorescence Immunoassay Analyser Operation Manual for the complete instructions on use of the Test. The test should be conducted at room temperature.
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. **Serum/plasma**: Transfer 20 µl of serum/plasma into the buffer tube, mix the specimen and the buffer well.
4. **Add diluted specimen with a Pipette**: Pipette 75 µl of diluted specimen into the sample well of the test cassette. Start the timer at the same time.
5. There are two test modes for the Biopanda Fluorescence Immunoassay Analyser; Standard Test mode and Quick Test mode. Please refer to the user manual of the Biopanda Fluorescence Immunoassay Analyser for details.

"Quick test" mode: Insert the test cassette into the Analyser at 15 minutes after sample application and click "New Test", the Analyser will automatically give the test result after a few seconds.
"Standard test" mode: Insert the test cassette into the Analyser immediately after sample application, click "New test" at the same time, the Analyser will automatically count down the 15 minutes. After the

countdown, the Analyser will give the result at once.

INTERPRETATION OF RESULTS

The result of tests for PSA is calculated by the Biopanda Fluorescence Immunoassay Analyser and displays the result on the screen. For additional information, please refer to the user manual of the Biopanda Fluorescence Immunoassay Analyser.

Linearity range of the Biopanda PSA FIA Rapid Test is 2-100 ng/ml.
Reference range: <4ng/ml.

QUALITY CONTROL

Each Biopanda PSA FIA Rapid Test Cassette contains an 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 device was inserted and read properly by the Biopanda Fluorescence Immunoassay Analyser. An invalid result from the internal control causes an error message on the Biopanda Fluorescence Immunoassay Analyser 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.

LIMITATIONS

1. The Biopanda PSA FIA Rapid Test Cassette is for professional *in vitro* diagnostic use, and should only be used for the quantitative detection of PSA.
2. The Biopanda PSA FIA Rapid Test Cassette will only indicate the presence of 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 that 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. PSA levels may be unreliable in patients who receive hormone therapy or prostate gland manipulation.
5. High concentrations of PSA may produce a dose hook effect, resulting in false negative results.
6. As with all diagnostic tests, a confirmed diagnosis should only be made by a physician after all clinical and laboratory findings have been evaluated.
7. The results of the Biopanda PSA FIA Rapid Tests are based on measuring the levels of 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.

EXPECTED RESULTS

Concentrations	Clinical Reference
<4 ng/ml	Healthy
4~10 ng/ml	Gray zone
>10 ng/ml	Risk (low) of prostate cancer
10~20 ng/ml	Moderate risk of prostate cancer
>20 ng/ml	High risk of prostate cancer

PERFORMANCE CHARACTERISTICS

1. **ACCURACY**: The test deviation is ≤±15%.
2. **DETECTION RANGE**: 2-100 ng/ml.
3. **LINEARITY RANGE**: 2-100 ng/ml, R≥0.990
4. **PRECISION**

INTRA-LOT PRECISION

Within-run precision has been determined by using 10 replicates of 2 specimens containing 4 ng/ml and 10 ng/ml of PSA. C.V. is ≤ 15%.

INTER-LOT PRECISION

Between-run precision has been determined by using 10 replicates for each of three lots using 2 specimens containing 4 ng/ml and 10 ng/ml of PSA. C.V. is ≤ 15%.

INTERFERING SUBSTANCES

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

Ascorbic Acid: 200 mg/l Hemoglobin: 10 g/l Triglyceride: 30 g/l
Bilirubin: 1,000 mg/dl Uric Acid: 200 mg/l.

METHOD COMPARISON

The assay was compared with ARCHITECT PSA test with 100 samples. The correlation coefficient(r) is 0.990.

REFERENCES

1. Wang MC, Valenzuela LA, Murphy GP, et al., Purification of human prostate specificity antigen. Invest Urol 1979; 17: 159-163.
2. Christens A, Laurell CB, Lilja H. Enzymatic activity of prostate –specific antigen and its reaction with extracellular serine proteinase Inhibitors. Eur J Biochem 1990; 194:755-763.
3. Catalona WJ, Southurick PC, Slawin KM, et al., Comparison of percent free PSA, PSA density and age-specific PSA cut-offs for prostate cancer detection and staging. Urology 2000 Aug 1:56(2):255-60.
4. Vancangh PJ, De Nayer P, Sauvage P, et al., Free to total prostate-specific antigen (PSA) ratio is superior to total PSA in differentially benign prostate hypertrophy from prostate cancer. Prostate Supplement, 1996, 7:30-34.

Index of Symbols

	Attention, see instructions for use		Tests per kit		Do not reuse
	For in vitro diagnostic use only		Use by		Catalogue #
	Store between 4-30°C		Lot Number		Consult instructions
	Do not use if package is damaged		Manufacturer		

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

Biopanda Reagents Ltd.
Unit 14 Carrowreagh Business Park
Carrowreagh Road
Belfast, BT16 1QQ
United Kingdom
Tel: +44 (0) 28 95438774
E-mail: info@biopanda.co.uk
Website: www.biopanda.co.uk

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