PSA FIA Rapid Test

(Whole Blood/Serum/Plasma)

Catalogue Number: FIA-PSA-002

A rapid test for detecting Prostate Specific Antigen (PSA) in whole blood, 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 whole blood, serum or plasma.

BACKGROUND

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 "grey-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 tumour marker known for prostate cancer and prostate infection of Benign Prostatic Hyperplasia (BPH).[4]

TEST PRINCIPLE

The Biopanda PSA FIA Rapid Test detects PSA based on fluorescence immunoassay. The specimen moves through the strip from the specimen 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 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 PSA in the specimen 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 CONTENTS

- 10 x Foil wrapped PSA test cassettes
- 10 x Specimen collection tubes with dilution buffer
- 10 x Capillary droppers (for finger-prick whole blood only)
- 10 x Disposable droppers (for finger-prick whole blood only)
- 1 x ID card (PSA)
- 1 x Package Insert

REQUIRED BUT NOT PROVIDED

- Timer
- Centrifuge
- Pipette
- Biopanda Fluorescence Immunoassay Analyser

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 and heparin lithium can be used as the anticoagulant for collecting blood specimens.

For Finger-pricked Whole Blood Specimens, please refer to the DIRECTIONS FOR USE for further information.

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. 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 cassette 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 whole blood/serum/plasma specimens:</u>

i. Pipette **20 µl of whole blood/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 cassette. Start the timer at the same time.

4.2 <u>For finger-prick whole blood specimens:</u>

i. Wash hands with soap and warm water or clean finger with an alcohol pad. Allow to dry.
ii. Massage the hand without touching the puncture site by applying pressure down the hand towards the finger to be pricked. The middle or ring finger is recommended.
iii. Use a sterile lancet to puncture the skin. Wipe away the first sign of blood.
iv. Gently apply pressure from palm to the pricked finger so a rounded drop of blood forms over the puncture site.
v. Using the provided capillary dropper and ensuring the dropper is level, touch the open end to the rounded drop of blood <u>without</u>

squeezing the dropper bulb. The dropper will automatically collect the correct volume of blood (approx. 20 µl), *see Figure 1 below*.

vi. Dispense the whole blood specimen into the buffer tube by squeezing the dropper bulb.

vii. Close the tube cap and shake the tube for approximately **10 seconds** to mix the specimen and dilution buffer well.

viii. Using a disposable dropper, **draw the diluted specimen to the fill line** marked on the dropper (approx. 75 µl), then add to the specimen well (S) of the test cassette. Start the timer.

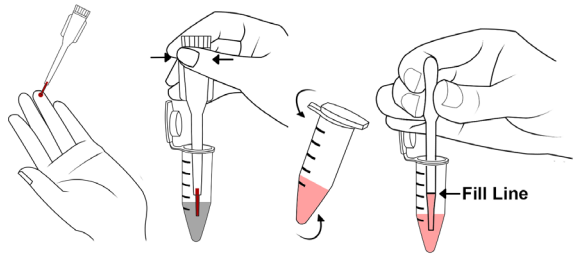

Figure 1

5. Test results should be read at **15 minutes** with the use of the Biopanda Fluorescence Immunoassay Analyser.

Note: The Biopanda Fluorescence Immunoassay Analyser 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 cassette 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 cassette 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 Analyser 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 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.

EXPECTED RESULTS

Concentrations	Clinical Reference
< 4 ng/ml	Healthy
≥ 4 ng/ml	Risk of prostate cancer

PERFORMANCE CHARACTERISTICS

1. **Accuracy**:
   The test deviation is ≤±15%
2. **Assay range:**
   0.1-100 ng/ml
3. **Minimum detection limit (analytical sensitivity)**:
   0.1 ng/ml
4. **Hook Effect:**
   No high-dose hook effect was detected at concentrations up to 300 ng/ml.
5. **Method comparison:**
   The assay was compared with a commercially available PSA test with 103 specimens. The correlation coefficient (r) is 0.9944.
6. **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	Triglyceride:	30 g/l
Bilirubin:	1,000 mg/dl	Uric Acid:	200 mg/l
Haemoglobin:	10 g/l		

Cross-reactivity

The Biopanda PSA FIA Rapid Test has been tested against AFP and CEA positive specimens. The results showed no cross-reactivity.

LIMITATIONS OF THE TEST

1. The Biopanda PSA FIA Rapid Test is for professional *in vitro* diagnostic use, and should only be used for the quantitative detection of PSA.
2. The test 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 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. 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.

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

	Manufacturer		Tests per kit		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 PSA FIA Rapid Test kit. Please read this manual carefully before operating to ensure proper use.

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