SAA FIA Rapid Test Device
(Whole Blood/Serum/Plasma)

Catalogue Number: FI2-SAA-001

A Fluorescence Immunoassay for the quantitative detection of serum amyloid A (SAA) in whole blood, serum, or plasma using the Biopanda Fluorescence Immunoassay Device (BR-FIA-2000).
For professional in vitro diagnostic use only.

INTENDED USE
The Biopanda SAA FIA Rapid Test Device is intended for *in vitro* quantitative determination of serum amyloid A protein (SAA) in whole blood, serum or plasma as an aid in the diagnosis of inflammatory conditions and immune status.

BACKGROUND
Serum amyloid A (SAA) is an acute phase protein with a relative molecular weight of 12,000. It is mainly produced by liver cells, but can also be produced outside the liver, such as the heart and skeletal muscle. Although both SAA and C-reactive protein (CRP) are acute-phase proteins, the detection of SAA is more conclusive than the detection of CRP in patients with viral infections, severe acute pancreatitis, and rejection reactions to kidney transplants.[1] After the human body is infected, it can rapidly increase by about 1000 times within 4-6 hours, and the half-life is 50 minutes.[2] After the pathogen is cleared. It can quickly drop to a normal level. It is a sensitive indicator that reflects the recovery of body infection and inflammation; the reference range of serum SAA is <10 mg/L, and its core clinical value lies in the identification of viral infections.

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

REAGENTS
The test kit includes anti-SAA antibody coated fluorophores and anti-SAA 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.
3. Do not use the test if the foil pouch is damaged.
4. Do not reuse tests.
5. Avoid cross-contamination of specimens by using a new specimen collection container for each specimen obtained.
6. 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 safety glasses when specimens are assayed.
7. Do not interchange or mix reagents from different lots.
8. Extreme in humidity and temperatures can adversely affect results.
9. Used testing materials should be discarded in accordance with local regulations.
10. The Biopanda SAA 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. Do not freeze.
3. The test must remain in the sealed pouch until use.
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 SAA rapid rest devices
- 25 x Specimen collection tubes with dilution buffer
- 25 x Capillary droppers
- 25 x Disposable droppers
- 1 x ID card (SAA)
- 1 x Package insert

EQUIPMENT REQUIRED BUT NOT PROVIDED
- Timer
- Centrifuge
- Pipette
- Biopanda Fluorescence Immunoassay Device (BR-FIA-2000)

SPECIMEN COLLECTION AND PREPARATION
1. Collect the specimen according to standard procedures.
2. Separate the serum or plasma from blood as soon as possible to avoid haemolysis. Only clear, non-haemolysed specimens can be used.
3. Do not leave specimens at room temperature for prolonged periods. Serum and plasma specimens may be stored at 2-8°C for up to 5 days; for long term storage, store below -20°C. Whole blood collected by venipuncture should be stored at 2-8°C if the test is to be run within 2 days of collection. Do not freeze whole blood specimens. Whole blood collected by finger-prick should be tested immediately.
4. Bring specimens to room temperature prior to testing. Frozen specimens must be completely thawed and mixed well prior to testing. Avoid repeated freeze-thaw cycles.
5. EDTA K2, heparin sodium, citrate sodium and potassium oxalate can be used as the anticoagulant for collecting the specimen.

***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 Device User Manual for the complete instructions on operating the device. The test should be conducted at room temperature. Cold buffer solution or moisture condensation on the membrane can lead to invalid test results.

Note: There are two test modes for the Biopanda Fluorescence Immunoassay Device: *Standard Test* mode and *Quick Test* mode.

***Standard Test* mode** is a 'set and forget' method where the test will automatically be read after 15 minutes.

***Quick Test* mode** provides an instant result but the user must monitor the 15 minute test time themselves. It is suitable when running multiple tests simultaneously.

Refer to the user manual for further information.

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

1. Turn on the analyzer and insert the ID card into the 'Code' port and wait for the 'ID card imported successfully' pop-up. Fill in the necessary details in the 'Test Info' section.
2. Remove the test device from the foil pouch and place it on a clean, level surface. Testing should start immediately after opening the foil pouch.
3. Follow the appropriate steps below for the prepared specimen type:
   a. **<u>For venipuncture whole blood/serum/plasma specimens:</u>**
      i. Pipette **10 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. **Pipette 75 µL of diluted specimen** into the specimen well (S) of the test device.
   b. **<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 (not provided) to puncture the skin and 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 capillary dropper provided and ensuring the dropper is level, touch the open end to the rounded drop of blood without squeezing the dropper bulb. **The dropper will automatically collect the correct volume of blood (approx. 10 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 device.

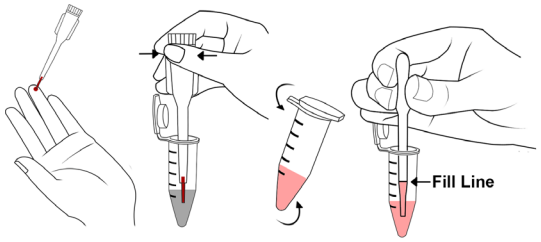

Figure 1

4. Insert the test device into the analyzer test device slot. Then according to user requirements, select either 'Standard test' or 'Quick test' mode.
5. **Test results should be read at 15 minutes** using the Biopanda Fluorescence Immunoassay Device (BR-FIA-2000).

INTERPRETATION OF RESULTS

The results are calculated by the Biopanda Fluorescence Immunoassay Device displayed on the analyzer screen. For additional information, please refer to the user manual.

Linearity range of the test is 0.1–300 mg/L.

EXPECTED RESULTS

Concentrations	Clinical Interpretation
<10mg/L	Normal reference range
10–100 mg/L	Presumed viral infection
100–500 mg/L	Presumed acute phase of bacterial infection
≥500 mg/L	Serious viral or bacterial infection

Note: The table above outlines the clinical implications associated with different SAA concentrations in the diagnosis of infectious diseases. SAA is a non-specific inflammatory marker; therefore, diagnostic conclusions should be made only in conjunction with other clinical findings and evidence.
It is recommended that each laboratory determine its own reference interval according to regional population characteristics, including age, sex, diet, and other relevant factors.

QUALITY CONTROL

Each Biopanda SAA FIA Rapid Test Device 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 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. An invalid result from the internal control causes an "N/A" message on the Biopanda Fluorescence Immunoassay Device. 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 device. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

PERFORMANCE CHARACTERISTICS

1. **Accuracy**
   The test deviation is ≤±15%.
2. **Assay Range and Detection Limit**
   - Assay Range: 1-300 mg/L
   - Minimum Detection Limit (Analytical Sensitivity): 1 mg/L
3. **Linearity Range**
   1-300 mg/L, R≥0.990
4. **Precision**

Intra-lot precision

Within-run precision has been determined by using 10 replicates of 2 specimens containing 10 mg/L and 100 mg/L of SAA. 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 10mg/L and 100mg/L of SAA. C.V. is ≤ 15%.

5. **Interfering substances**
   The following substances do not interfere with the test results at the indicated concentration: 50 ng/mL PCT, 100 mg/L CRP, 20 mg/dL bilirubin, 10 ng/mL IL-6, 1 g/dL haemoglobin.
6. **Method Comparison**
   A comparison study was conducted with the Biopanda SAA FIA Rapid Test Device and a commercially available SAA test with 80 samples. The correlation coefficient(R) is 0.990.

LIMITATIONS OF THE TEST

1. The Biopanda SAA FIA Rapid Test Device is for professional *in vitro* diagnostic use, and should only be used for the quantitative detection of SAA.
2. The test will only indicate the presence of SAA antigen in the specimen and should not be used as the sole criterion for evaluating inflammatory conditions.
3. Like with all diagnostic tests, a confirmed diagnosis should only be made by a physician after all clinical and laboratory findings have been evaluated.
4. High concentrations of SAA may produce a dose hook effect, which may result in the incorrect interpretation of SAA levels.
5. The results are based on measuring the levels of SAA 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 should be consulted to ensure proper medical treatment is provided.

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 SAA FIA Rapid Test Device. Please read this manual carefully before operating to ensure proper use.

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