IgA FIA Rapid Test Device
(Whole Blood/Serum/Plasma)
FI2-IGA-001

A rapid test for the quantitative detection of Immunoglobulin A (IgA) antibodies in Whole Blood, 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 IgA FIA Rapid Test Device is based on Fluorescence Immunoassay for the quantitative determination of Immunoglobulin A (IgA) antibodies in whole blood, serum or plasma.

SUMMARY
The spectrum of abnormalities in serum immunoglobulin concentrations is broad. Abnormal concentrations range from a virtual absence of one or more of the three major classes of immunoglobulin (IgG, IgA and IgM) to polyclonal increases in one or more immunoglobulins. Measurement of these immunoglobulins aids in the diagnosis of abnormal protein metabolism and the body's lack of ability to resist infectious agents.
The serum IgA has the immune function of certain IgG and IgM, specific IgA can neutralize the antigen in the blood, but also appear alternative complement immune system.[1]

PRINCIPLE
The IgA FIA Rapid Test Device is a quantitative membrane-based fluorescence immunoassay for the detection of IgA in human whole blood, serum or plasma specimen. During testing, the sample moves through the strip from sample pad to absorbent pad. IgA in the sample will compete with the IgA antigen coated on the membrane. The less IgA in the sample, the more fluorescent microspheres conjugated with anti-IgA antibodies can be captured by the IgA antigen coated on the membrane (Test line). The concentration of IgA in the sample is inversely related to the intensity of the fluorescent signal captured on the T line. According to the fluorescence intensity of the test and the standard curve, the concentration of IgA in the sample can be calculated by the fluorescence immunoassay device. The testing result of IgA will be displayed on the device screen.

REAGENTS
The test contains IgA antigen coated with cellulose nitrate membrane and anti-IgA antibody which conjugated with fluorescence particles.

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 IgA FIA Rapid Test should only be used with the Biopanda Fluorescence Immunoassay Device 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
- 25 x foil wrapped IgA FIA Rapid Test Devices
- 25 x Specimen collection tubes with dilution buffer
- 1 x ID card (IgA)
- Package Insert

MATERIALS 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 the serum or plasma from blood as soon as possible to avoid hemolysis. Only clear, non-hemolyzed 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 3 days, for long term storage, specimens should be kept 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 fingerstick 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 freezing and thawing of specimens.
5. EDTA K2, Heparin sodium, Sodium citrate, and Oxalate potassium can be used as the anticoagulant for collecting the specimen. A clean tube without anticoagulants can be used to collect serum 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 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.

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 concurrently.
Refer to the Biopanda Fluorescence Immunoassay Device Operation Manual for further details.

Allow the test cassette, specimen, buffer and/or controls to reach room temperature (15-30°C) prior to testing.
1. Turn on the Analyser. Then according to users' requirements, 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:
   a. **For venipuncture whole blood/serum/plasma specimens:**
      Whole blood/Serum/plasma: Transfer 10 µl of whole blood/ serum/ plasma into the buffer tube, mix the specimen and the buffer well.
      Add diluted specimen with a Pipette: Pipette 75 µl of diluted specimen into the sample well of the test device. Start the timer at the same time.
   b. **For finger-prick whole blood specimens:**
      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 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 cassette. Start the timer.

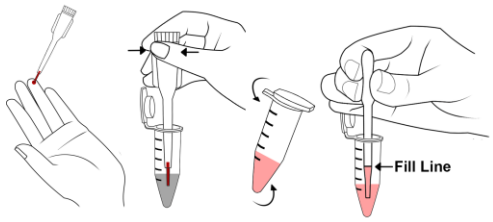

Figure 1

5. Test results should be read at **15 minutes** with the use of the Biopanda Fluorescence Immunoassay Device (BR-FIA-2000).

INTERPRETATION OF RESULTS

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

Linearity range of the Biopanda IgA FIA Rapid Test is 0.1-7.0 g/L.
Reference range: 0.7-4.3 g/L.

QUALITY CONTROL

Each Biopanda IgA 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. 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 IgA FIA Rapid Test Device is for professional *in vitro* diagnostic use and should only be used for the quantitative detection of IgA. The test works only when the test procedures are precisely followed.
2. Like with all diagnostic tests, a confirmed diagnosis should only be made by a physician after all clinical and laboratory findings have been evaluated.
3. The results of IgA Tests are based on measuring the levels of IgA 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.
4. The hematocrit level of the whole blood can affect the test results. Hematocrit level needs to be between 25% and 65%.

EXPECTED RESULTS

Values (g/L)	Interpretation
<0.7	Below
0.7-4.3	Normal
>4.3	High

Note: Each laboratory should determine the applicability of the reference range through experiments and establish its own reference value range if necessary to ensure that it can correctly reflect the situation of a particular population.

PERFORMANCE CHARACTERISTICS

1. **ACCURACY**: The test deviation is ≤±15%.
2. **SENSITIVITY**: The Biopanda IgA FIA Rapid Test can detect levels of IgA as low as 0.1 g/L in whole blood, serum or plasma.

3.Precision

Intra-Assay

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

Inter-Assay

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

4.Cross-reactivity

The IgA FIA Rapid Test Device has been tested for IgG, IgM and IgE at 20 g/L, 2 µg/L and 1600 IU/mL. The results showed no cross-reactivity.

5.Interfering Substances

The following compounds have been tested using the IgA FIA Rapid Test Device and no interference was observed.
Triglyceride: 100 mg/dL Ascorbic Acid: 20 mg/dL Hemoglobin: 1000 mg/dL
Bilirubin: 60 mg/dL Total cholesterol: 15 mmol/L

6.Detection Range

The Detection range of the IgA FIA Rapid Test Device is 0.1-7.0 g/L.

7.Method comparison

For 96 specimens, the test results of IgA FIA Rapid Test Device were consistent with a commercial test kits, and correlation coefficient (R) is 0.987.

REFERENCES

1. Pabst, Oliver. "New concepts in the generation and functions of IgA."Nature Reviews Immunology 12.12 (2012): 821-832

Index of Symbols

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

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

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