IgE FIA Rapid Test Device

(Whole Blood/Serum/Plasma)

FI2-IGE-001

A rapid test for detecting Immunoglobulin E (IgE) 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 IgE FIA Rapid Test Device is based on Fluorescence Immunoassay for the quantitative determination of Immunoglobuling E (IgE) antibodies in whole blood, serum or plasma.

SUMMARY

Immunoglobulin E (IgE) is a type of antibody (or immunoglobulin (Ig) "isotype") that has only been found in mammals. IgE is synthesised by plasma cells. Monomers of IgE consist of two heavy chains (ε chain) and two light chains, with the ε chain containing 4 Ig-like constant domains (Cε1-Cε4).[1] IgE's main function is immunity to parasites such as helminths[2] like *Schistosoma mansoni, Trichinella spiralis, and Fasciola hepatica*. [3,4,5] IgE is utilized during immune defense against certain protozoan parasites such as *Plasmodium falciparum*.[6] IgE also has an essential role in type I hypersensitivity,[7] which manifests in various allergic diseases, such as allergic asthma, most types of sinusitis, allergic rhinitis, food allergies, and specific types of chronic urticaria and atopic dermatitis. IgE also plays a pivotal role in responses to allergens, such as: anaphylactic drugs, bee stings, and antigen preparations used in desensitization immunotherapy.

Although IgE is typically the least abundant isotype—blood serum IgE levels in a normal ("non-atopic") individual are only 0.05% of the Ig concentration,[8] compared to 75% for the IgGs at 10 mg/ml, which are the isotypes responsible for most of the classical adaptive immune response - it is capable of triggering the most powerful inflammatory reactions.

PRINCIPLE

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

REAGENTS

The test includes anti-IgE antibody coated fluorophores and anti-IgE 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 IgE 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 IgE FIA Rapid Test Devices
- 25 x Specimen collection tubes with dilution buffer
- 25 x Capillary Droppers
- 25 x Disposable Droppers
- 1 x ID card (IgE)
- Package Insert

MATERIALS REQUIRED BUT NOT PROVIDED

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

SPECIMEN COLLECTION AND PREPARATION

PREPARATION

1. Before performing the test, please make sure that all components are brought to room temperature (15-30^{o}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.

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 1 day, 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 used within 1 day of collections. Do not freeze whole blood specimens. Whole blood collected by finger stick should be tested immediately.
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 K2, Heparin sodium, Citrate sodium, and Oxalate potassium can be used as the anticoagulant for collecting the blood specimen.

SAMPLE DILUTION / SAMPLE STABILITY

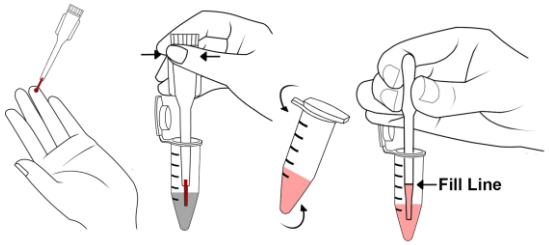
1. Transfer **75 µL of whole blood, serum or plasma** to the buffer tube with a micro pipette.
2. Close the tube and shake the sample by hand vigorously for approximately **10 seconds** to mix the sample and dilution buffer.
3. Let the diluted sample homogenize for approximately 1 minute.
4. The diluted sample can then be used immediately or stored for up to 8 hours on an ice pack if not used immediately. Allow sample to return to room temperature before testing.

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.

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. **Whole Blood, serum/plasma**: Transfer 75 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 Device. Start the timer at the same time.



5. There are two test modes for the Biopanda Fluorescence Immunoassay Device; Standard Test mode and Quick Test mode. Please refer to the user manual of the Biopanda Fluorescence Immunoassay Device for details.

"Quick test" mode: Insert the test Device 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 Device 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 IgE 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 IgE FIA Rapid Test is 20 – 1600 IU/ml.

QUALITY CONTROL

Each Biopanda IgE 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 IgE FIA Rapid Test Device is for professional *in vitro* diagnostic use and should only be used for the quantitative detection of IgE. The test works only when the test procedures are precisely followed.
2. The Biopanda IgE FIA Rapid Test Device will only indicate the presence of IgE in the specimen and the test may not be used as sole criterion.
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. The results of IgE Tests are based on measuring the levels of IgE 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

Concentration	Reference Range (mIU/ml)
≤100 IU/ml	Reference value
>100 IU/ml	Abnormal value/possible allergic response

Note: The establishment of the reference interval for this test device is only for specimens from local populations. It is recommended that each laboratory establish an actual reference interval based on the population, age, gender, diet, etc. in each region.

PERFORMANCE CHARACTERISTICS

1. **ACCURACY**: The test deviation is ≤±15%.
2. **SENSITIVITY**: The Biopanda IgE FIA Rapid Test can detect levels of IgE as low as 20 IU/mL in whole blood, serum or plasma.
3. **DETECTION RANGE**: 20-1600 IU/mL.
4. **LINEARITY RANGE**: 20-1600 IU/mL, R≥0.990
5. **Precision**

   Intra-lot precision

   C.V. is ≤ 15%

   Inter-lot precision

   C.V. is ≤ 20%
6. **CROSS-REACTIVITY**

There was no cross-reactivity with IgG and IgM at the concentration of 20g/l and 2ug/L respectively.

7. **INTERFERING SUBSTANCES**

The following potentially interfering substances were tested on IgE Test Cassette.

Ascorbic Acid: 50mg/dL Bilirubin: 200mg/dL

Glucose: 600mg/dL Triglycerides: 1,600mg/dL

None of the substances at the concentration tested interfered in the assay.

REFERENCES

1. "Antibody structure". Archived from the original on September 6, 2008.
2. Erb KJ (2007). "Helminths, allergic disorders and IgE-mediated immune responses: where do we stand?". Eur. J. Immunol. 37 (5): 1173.
3. Fitzsimmons CM, McBeath R, Joseph S, Jones FM, Walter K, Hoffmann KF, Kariuki HC, Mwatha JK, Kimani G, Kabatereine NB, Vennervald BJ, Ouma JH, Dunne DW (2007). "Factors affecting human IgE and IgG responses to allergen-like Schistosoma mansoni antigens: Molecular structure and patterns of in vivo exposure". Int. Arch. Allergy Immunol. 142 (1): 40–50.
4. Watanabe N, Bruschi F, Korenaga M (2005). "IgE: a question of protective immunity in Trichinella spiralis infection". Trends Parasitol. 21 (4): 175–8.
5. Pfister K, Turner K, Currie A, Hall E, Jarrett EE (1983). "IgE production in rat fascioliasis". Parasite Immunol. 5 (6): 587–93.
6. Duarte J, Deshpande P, Guiyedi V, Mécheri S, Fesel C, Cazenave PA, Mishra GC, Kombila M, Pied S (2007). "Total and functional parasite specific IgE responses in Plasmodium falciparum-infected patients exhibiting different clinical status". Malar. J. 6:
7. Gould HJ, Sutton BJ, Beavil AJ, Beavil RL, McCloskey N, Coker HA, Fear D, Smurthwaite L (2003). "The biology of IgE and the basis of allergic disease". Annu. Rev. Immunol. 21: 579–628.
8. Winter WE, Hardt NS, Fuhrman S (2000). "Immunoglobulin E: importance in parasitic infections and hypersensitivity responses".Arch. Pathol. Lab. Med.124 (9): 1382–5.

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 IgE FIA Rapid Test Device. 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

Effective date: 02/05/2025