

Rheumatoid Factor IgM FIA Rapid Test Device (Whole Blood/Serum/Plasma)

FI2-RFT-001

A rapid test for the quantitative detection of Rheumatoid Factor IgM (RF-IgM) in whole blood or serum or plasma that can be performed with the use of the Biopanda Fluorescence Immunoassay Device (BR-FIA-2000).

For professional in vitro diagnostic use only.

INTENDED USE

The Rheumatoid Factor IgM FIA Rapid Test Device is intended for *in vitro* quantitative determination of RF-IgM in human whole blood, serum or plasma. Measurement of RF-IgM is used as an aid to assessment of Rheumatoid Arthritis.

SUMMARY

Rheumatoid factor (RF) is an autoantibody most relevant in rheumatoid arthritis. It is an antibody against the Fc portion of IgG, which is itself an antibody. RF is often evaluated in patients suspected of having any form of arthritis even though positive results can be due to other causes. It is part of the usual disease criteria of rheumatoid arthritis, and RF may serve as one of several serological markers for autoimmunity unrelated to rheumatoid arthritis.¹ High levels of rheumatoid factor (generally above 20 IU/mL) occur in rheumatoid arthritis (present in 80%) and Sjögren's syndrome (present in 70%).^{2,3} Rheumatoid factor (RF) have several common types of IgM, IgG, IgA and IgE of which the IgM is most common and used regularly to assess rheumatoid factor.

PRINCIPLE

The Rheumatoid Factor IgM FIA Rapid Test Device detects Rheumatoid Factor IgM (RF-IgM) based on Fluorescence Immunoassay. During testing, the specimen moves through the strip from sample pad to absorbent pad. RF-IgM in the specimen will be combined with the anti-Human IgM antibody that is conjugated with fluorescence microspheres and the combination will be captured by human denatured IgG coated on the membrane. The more RF-IgM in the specimen, the more fluorescent microspheres is captured on the membrane. The concentration of RF-IgM in the specimen is 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 RF-IgM in the specimen can be calculated and reported by the Biopanda Fluorescence Immunoassay Device (BR-FIA-2000).

REAGENTS

The test kit includes anti-Human IgM antibody coated particles and human denatured IgG 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. This test contains products of animal origin. Certified knowledge of the origin and/or sanitary state of the animals does not completely guarantee the absence of transmissible pathogenic agents. It is therefore recommended that these products be treated as potentially infectious, and handled observing usual safety precautions (e.g., do not ingest or inhale).
4. Avoid cross-contamination of specimens by using a new specimen collection container for each specimen obtained.
5. 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.
6. Do not interchange or mix reagents from different lots.
7. Humidity and temperature can adversely affect results.
8. Used testing materials should be discarded in accordance with local regulations.
9. Read the entire procedure carefully prior to any testing.
10. The Biopanda Rheumatoid Factor IgM FIA Rapid Test 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. 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 Rheumatoid Factor IgM test devices
- 25 x Specimen collection tubes with extraction buffer
- 25 x Capillary Droppers
- 25 x Disposable Droppers
- 1 x ID card (RF-IgM)
- Package Insert

MATERIALS REQUIRED BUT NOT PROVIDED

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

SPECIMEN COLLECTION

1. Collect the specimen according to standard procedures.
2. Do not leave the 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. Blood collected from fingerstick samples should be used immediately.
3. Bring specimens to room temperature prior to testing. Frozen specimens must be completely thawed and mixed well prior to testing. Specimens should not be frozen and thawed repeatedly.
4. EDTA, Sodium Citrate, and Potassium Oxalate can be used as the anticoagulant tube for collecting the blood specimen.

DIRECTIONS FOR USE

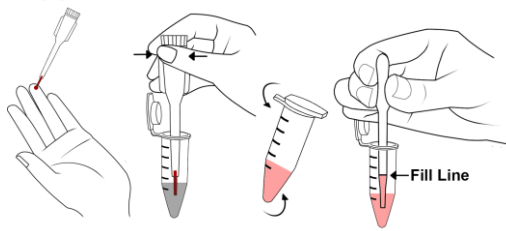
Refer to the Biopanda Fluorescence Immunoassay Device Operation Manual for the complete instructions on use of the test. The test should be conducted at room temperature. Cold buffer solution or moisture condensation on the membrane can lead to invalid test results.

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 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. **Whole blood/Serum/plasma:** Transfer 10 µl of **Whole blood, serum, or plasma** into the buffer tube, mix the specimen and the buffer well.
5. **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.



- 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 RF-IgM 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.

Results are reported as the numerical value with unit IU/mL and results with Neg./Pos. (shorted from Negative/Positive)

The detection range of Rheumatoid Factor IgM Test Cassette is 8-200 IU/mL. Normal Reference range: <20 IU/mL.

QUALITY CONTROL

Each Biopanda Rheumatoid Factor IgM 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 test. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

LIMITATIONS

- The Rheumatoid Factor IgM FIA Rapid Test Device should be used only with the Biopanda Fluorescence Immunoassay Device.
- The test should preferably be performed on freshly collected specimens. For stored specimens, please refer to specimen storage.
- The Rheumatoid Factor IgM FIA Rapid Test Device is for professional *in vitro* diagnostic use, and should only be used for the quantitative detection of RF-IgM.
- The Rheumatoid Factor IgM FIA Rapid Test Device will only indicate the presence of Rheumatoid Factor IgM in the specimen and should not be used as the sole criteria for clinical result.
- As with all diagnostic tests, a confirmed diagnosis should only be made by a physician after all clinical and laboratory findings have been evaluated.
- Grossly hemolyzed, icteric or lipemic specimens should be avoided.

EXPECTED RESULTS

Concentrations	Clinical Reference
<20 IU/mL	Negative
≥20 IU/mL	Positive

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. Method comparison

For 109 specimens, the test results of the Rheumatoid Factor IgM FIA Rapid Test Device were consistent with a commercial test kits, and correlation coefficient (R) is 0.969.

2. Accuracy

The test deviation ≤ ±15%.

3. Assay Range

Assay Range is 8-200 IU/mL.

4. Precision

Intra-lot precision

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

Inter-lot precision

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

REFERENCES

- Rostaing L, Modesto A, Cisterne JM, Izopet J, Oksman F, Duffaut M, Abbal M, Durand D. "Serological markers of autoimmunity in renal transplant patients with chronic hepatitis C". American journal of nephrology 18 (1): 50 – 56, 1998.
- Goodyear CS, et al. Rheumatoid factors and other autoantibodies in rheumatoid arthritis. In: Firestein GS, et al. Kelley's Textbook of Rheumatology. 8th ed. Philadelphia, Pa.: W.B.Saunders Elsevier; 2008.
- Shmerling RH. Origin and utility of measurement of rheumatoid factors. <http://www.uptodate.com/home/index.html>. Accessed Aug. 19, 2010.

Index of Symbols

	Manufacturer		Tests per kit		Do not reuse test
	<i>In vitro</i> diagnostic medical device		Expiration date		Catalogue number
	Storage temperature		Lot Number		Consult instructions for use
	Do not use if package is damaged				

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



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