CRP FIA Rapid Test Device

(Whole Blood/Serum/Plasma)

Catalogue Number: FI2-CRP-001

A Fluorescence Immunoassay for the quantitative detection of CRP/hs-CRP 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 CRP FIA Rapid Test Device is based on Fluorescence Immunoassay for the quantitative determination of C-reactive protein (CRP) in whole blood, serum or plasma as an aid in the evaluation of infection, tissue injury and inflammatory disorders along with measurement of high sensitivity CRP (hs-CRP) for evaluation of acute coronary syndromes (ACS).

BACKGROUND

C-reactive protein is an acute-phase reactant that precipitated with Pneumococcal C-polysaccharide, and is a non-specific immune response component. CRP has wide distribution in our body, and is an acute-phase protein produced in the liver in response to microbial infection or tissue injury, it measures general levels of inflammation in the body, and the hs-CRP can be used to detect lower concentrations of CRP in serum or plasma. Studies revealed hs-CRP levels seem to be correlated with Atherosclerosis and Acute Myocardial Infarction. And the hs-CRP is an inflammation "marker" for ACS patient and is helpful for primary prevention and risk assessment of cardiovascular disease. Its combination with the ratio of total cholesterol to HDL-C is more accurate than other risk factors in predicting cardiovascular disease.
The American Heart Association and US Centers for Disease Control and Prevention have advocated hs-CRP as a predictor of cardiovascular disease (CVD) to define risk groups: less than 1.0 mg/L indicates low risk, 1.0 to 3.0 mg/L means moderate risk, and the amount above 3.0 mg/L (lower than 10 mg/L) strongly suggests a high risk of CVD. Moreover, higher CRP levels are found in late pregnant women, mild inflammation and viral infections (10-40 mg/L), active inflammation, bacterial infection (40-200 mg/L), severe bacterial infections and burns (>200 mg/L).

TEST PRINCIPLE

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

REAGENTS

The test kit includes anti-CRP antibody coated fluorophores and anti-CRP 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.
7. 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.
8. Do not interchange or mix reagents from different lots.
9. Extreme humidity and temperatures can adversely affect results.
10. Used testing materials should be discarded in accordance with local regulations.
11. The Biopanda CRP 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. Do not freeze.
2. The test must remain in the sealed pouch until use.
3. 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 CRP test devices
- 25 x Capillary droppers (for finger-prick whole blood only)
- 25 x Disposable droppers
- 25 x Specimen collection tubes with dilution buffer
- 1 x ID card (CRP)
- 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 3 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 repeat freeze-thaw cycles.
5. EDTA and heparin sodium can be used as the anticoagulant for collecting the blood 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 3 minutes.

***Quick Test* mode** provides an instant result but the user must monitor the 3 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. **For serum/plasma specimens:**
      i. **Transfer 5 µL of serum or 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 of the test device.

b. <u>For venipuncture whole blood specimens:</u>

i. **Transfer 7.5 µL of whole blood** 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.

c. <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 <u>without</u> squeezing the dropper bulb. The dropper will automatically collect the correct volume of blood (approx. 7.5 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.

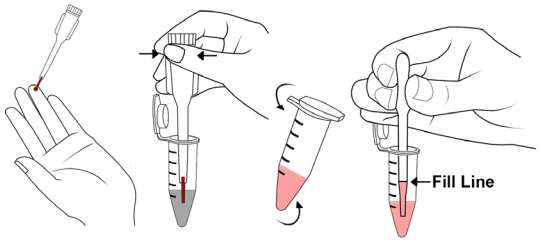

Figure 1

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 3 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 0.5-200 mg/L.

EXPECTED RESULTS

Concentrations	Clinical Reference
<1.0 mg/L	Low CVD risk
1.0-3.0 mg/L	Moderate CVD risk (no inflammation)
>3.0 mg/L	High CVD risk (no inflammation)
>10 mg/L	Probable infection (bacterial or viral infection)
10-20 mg/L	Generally indicates viral or mild bacterial infections
20-50 mg/L	Generally indicates moderate bacterial infection
>50 mg/L	Generally indicates serious bacterial infection

QUALITY CONTROL

Each Biopanda CRP 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.

PERFORMANCE CHARACTERISTICS

1. **Accuracy**: The test deviation is ≤±15%.
2. **Sensitivity**:
   The Biopanda CRP FIA Rapid Test Device can detect levels of CRP as low as 0.5 mg/L in whole blood, serum or plasma.
3. **Detection range**: 0.5-200 mg/L
4. **Linearity range**: 0.5-200 mg/L, R≥0.990
5. **Precision:**

Intra-lot precision

Within-run precision has been determined by using 10 replicates of 2 specimens containing 1.0 mg/L, 10.0 mg/L of CRP. 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 1.0 mg/L, 10.0 mg/L of CRP. C.V. is ≤15%.

LIMITATIONS OF THE TEST

1. The Biopanda CRP FIA Rapid Test Device is for professional *in vitro* diagnostic use, and should only be used for the quantitative detection of CRP in whole blood, serum and plasma.
2. The test will only indicate the presence of CRP antigen in the specimen and should not be used as the sole criterion for evaluating inflammatory conditions.
3. As 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 CRP may produce a dose hook effect, resulting in incorrect interpretation of CRP levels. High dose hook effect has not been observed with this test up to 200 mg/L of CRP.
5. The test results are based on measuring the levels of CRP 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 method results should be considered before confirming diagnosis.

INDEX OF SYMBOLS

	Manufacturer		Tests per kit		Do not reuse test
IVD	*In vitro* diagnostic medical device		Expiration date	REF	Catalogue number
	Storage temperature	LOT	Lot Number		Consult instructions for use
	Do not use if package is damaged				

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

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