CRP FIA Rapid Test

(Whole Blood/Serum/Plasma)

FIA-CRP-001

A rapid test for the diagnosis of inflammatory conditions and ACS by measuring CRP/hs-CRP in whole blood, serum, or plasma with the use of the Biopanda Fluorescence Immunoassay Analyser.
For professional in vitro diagnostic use only.

INTENDED USE

The CRP FIA Rapid Test 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).

SUMMARY

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).

PRINCIPLE

The CRP FIA Rapid Test Cassette 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 Analyser 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. 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 CRP FIA Rapid Test should only be used with the Biopanda `Fluorescence Immunoassay Analyser 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

- 10 x foil wrapped CRP test cassettes
- 10 x Capillary sample collection device/dropper
- 10 x Specimen collection tubes with dilution buffer
- 1 x ID card (CRP)
- Package Insert

MATERIALS REQUIRED BUT NOT PROVIDED

- Timer
- Centrifuge
- Pipette
- Biopanda Fluorescence Immunoassay Analyser

SPECIMEN COLLECTION AND PREPARATION

PREPARATION

1. Before performing the test, please make sure that all components are brought to room temperature (15-30°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. Open the screw cap.

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 run within half-day of collection. 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. Only clear, non-haemolysed specimens can be used.
4. EDTA and Heparin sodium, can be used as the anticoagulant for collecting the specimen.

SAMPLE DILUTION / SAMPLE STABILITY

1. Administer the blood-filled end-to-end capillary into the plastic tube with buffer. Alternatively, the specimen (5 µl of serum or plasma /7.5 µl of whole blood) can be added directly with a micro pipette into the buffer.
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.

DIRECTIONS FOR USE

Refer to the Biopanda Fluorescence Immunoassay Analyser 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. **Serum/plasma**: Transfer 5 µl of serum/plasma into the buffer tube, mix the specimen and the buffer well.
   Whole blood: Transfer 7.5 µl of whole blood into the buffer tube with pipette; mix the specimen and the buffer thoroughly.
4. **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. **Add specimen with sampler provided:** Discard the first 2 drops, then **add 2 drops of diluted specimen** into the sample well of the cassette. Start the timer at the same time.
5. There are two test modes for the Biopanda Fluorescence Immunoassay Analyser; Standard Test mode and Quick Test mode. Please refer to the user manual of the Biopanda Fluorescence Immunoassay Analyser for details.

"Quick test" mode: Insert the test cassette into the Analyser at 3 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 cassette into the Analyser immediately after sample application, click "New test" at the same time, the Analyser will automatically count down the 3 minutes. After the countdown, the Analyser will give the result at once.

INTERPRETATION OF RESULTS

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

Linearity range of the Biopanda CRP FIA Rapid Test is 0.5-200 mg/L.

QUALITY CONTROL

Each Biopanda CRP FIA Rapid Test Cassette 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 Analyser. An invalid result from the internal control causes an error message on the Biopanda Fluorescence Immunoassay Analyser indicating that the test should be repeated. An invalid result from the internal control causes an "N/A" message on the Biopanda Fluorescence Immunoassay Analyser. 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 CRP FIA Rapid Test Cassette is for professional *in vitro* diagnostic use, and should only be used for the quantitative detection of CRP.
2. The Biopanda CRP FIA Rapid Test Cassette 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 results of the Biopanda CRP FIA Rapid Tests 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 methods are recommended to reach proper medical treatments.

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

PERFORMANCE CHARACTERISTICS

1. **ACCURACY**: The test deviation is ≤±15%.
2. **SENSITIVITY**: The Biopanda CRP FIA Rapid Test Cassette 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%.

REFERENCES

1. Morley JJ, Kushner (1982) Serum C-reactive protein levels in disease. In: Kushner I, Volanakis JE, Gewurz H,eds. C-reactive protein and the plasma protein response to tissue injury. Ann. NY Acad. Sci. 389: 406-417.
2. Peltola HO (1982) C-reactive protein for rapid monitoring of infections of the central nervous system. Lancet:980-983.
3. Macy EM, Hayes TE and Tracy RP (1997) Variability in the measurement of C-reactive protein in healthy subjects: implications for reference intervals and epidemiological applications. Clin. Chem. 43, 52-58.

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. Please read this manual carefully before operating to ensure proper use.

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