CRP Rapid Test

Catalogue Number: RAPG-CRP-002

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

TEST KIT DESCRIPTION

The Biopanda CRP Rapid Test is a lateral flow chromatographic immunoassay for the qualitative detection of human C-reactive protein (CRP) in whole blood, serum, and plasma samples. This test is a tool to assist in the diagnosis of inflammatory conditions. The cut-off value for this test is 10 mg/L.

SUMMARY

C-reactive Protein (CRP) in patient's sera has been found in association with acute infections, necrotic conditions and a variety of inflammatory disorders. There is a strong correlation between serum levels of CRP and the onset of the inflammatory process. Monitoring the levels of CRP in patient's sera indicates the effectiveness of treatment and the assessment of patient recovery. It is used in particular to differentiate bacterial infections from viral infections.

PRINCIPLE

The Biopanda CRP Rapid Test is a qualitative, membrane based immunoassay for the detection of CRP in whole blood, serum or plasma. The membrane is pre-coated with specific capture antibodies in the test line regions of the test. During testing, the whole blood, serum or plasma specimen reacts with the particle coated with specific antibodies. The mixture migrates laterally along the membrane chromatographically by capillary action to react with specific capture reagents on the membrane and generate a coloured line. The presence of this coloured line in the specific test line region indicates a positive result, while its absence indicates a negative result. To serve as a procedural control, a coloured line will always appear in the control line region indicating that proper volume of specimen has been added and membrane wicking has occurred.

KIT CONTENTS

- 10 x Foil wrapped cassettes containing dropper and desiccant.
- 10 x Buffer Tubes
- 10 x Capillary tubes
- 1 x Product insert

STORAGE AND STABILITY

Store the kit between 2-30°C and ensure the kits are not frozen or stored in direct sunlight. The test is valid until the expiration date printed on the foil wrapping. Keep tests inside the foil pouch until use.

PRECAUTIONS

Follow these instructions for the best results:

- For professional *in vitro* diagnostic use only.
- 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 tests.
- This kit 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).
- Avoid cross-contamination of specimens by using a new specimen collection container for each specimen obtained.
- Read the entire procedure carefully prior to any testing.
- Do not eat, drink or smoke in the area where the specimens and kits 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.
- Do not interchange or mix reagents from different lots.
- Humidity and temperature can adversely affect results.
- Used testing materials should be discarded in accordance with local regulations.

SAMPLE COLLECTION AND 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 buffer tube out of the kit. Label it with patient's ID. Open the screw cap.

Blood Sample Collection

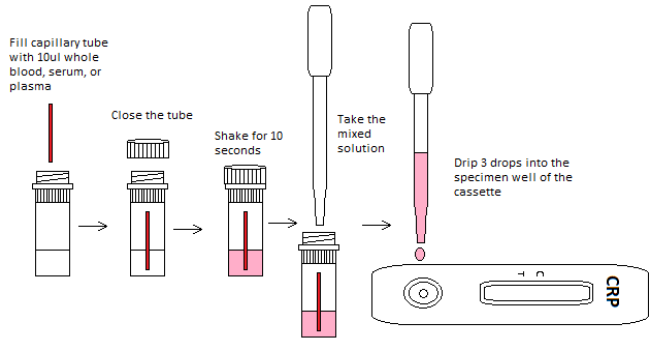
1. Collect the specimen according to standard procedures.
2. Do not leave specimens at room temperature for prolonged periods. Serum and plasma specimens may be stored at 2-8°C for up to 3 days. For long term storage, specimens should be kept below -20°C. Whole blood collected by venipuncture should be stored at 2-8°C if the test is to be used within 2 days 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.
4. EDTA-, citrate- or heparin blood can be used as well. Before performing the test, it has to be diluted accordingly with the supplied buffer.

Specimen Dilution / Stability

1. With the capillary tube, aspirate 10 µl of blood. It is important that the capillary is filled end to end to ensure 10 µl of blood.
2. Place the end-to-end blood-filled capillary into the dilution buffer vial. Alternatively, the 10 µl of specimen can be added directly with the micro pipette into the dilution buffer vial.
3. Close the vial and shake the sample vigorously for approximately 10 seconds so that sample and dilution buffer mix well. (See illustration)
4. Let the diluted sample rest for approximately 1 minute.
5. The diluted specimen can then be used immediately or stored for up to 8 hours.

TEST PROCEDURE

1. Ensure specimen and test kits are brought to room temperature before testing.
2. Open the foil wrapped pouch and remove the cassette, placing it on a flat, clean surface. Use the test as soon as possible or within one hour of opening.
3. Hold the dropper vertically and transfer 3 drops of the diluted specimen (approx 120 µl) to the specimen well of the cassettes and start the timer.
4. Wait for the coloured line(s) to appear. Read results at 5 minutes. Results read after 10 minutes are considered invalid.



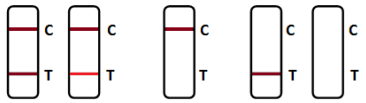
TEST RESULTS

POSITIVE:* Two lines appear. One coloured line should be in the control line region (C) and another apparent coloured line should be in the test line region (T).

***NOTE:** The intensity of the colour in the test line region (T) will vary depending on the concentration of CRP antigen present in the specimen. Therefore, any shade of colour in the test line region (T) should be considered positive.

NEGATIVE: One coloured line appears in the control line region (C). No line appears in the test line region (T).

INVALID: Control line fails to appear. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line 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.



Positive Negative Invalid

LIMITATIONS OF THE PROCEDURE

1. The Biopanda CRP Rapid Test is for professional *in vitro* diagnostic use, and should only be used for the qualitative detection of C - reactive protein.
2. This test will only indicate the qualitative level of CRP in the specimen and should not be used as the sole criteria for evaluating inflammatory conditions.
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. 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 2,000 mg/L of CRP.
5. The hematocrit of the whole blood should be between 25% and 65%.

EXPECTED VALUES

CRP plasma levels increase within 6 to 8 hours after occurrence of an acute event, for example a bacterial infection or trauma and reach their peak within approximately 48 hours after the occurrence of an event. The levels fall quickly after the causing event stops, with a CRP half-life of 48 hours.
Usually, the severity of the inflammation and the inflammation activity influence the extent of the CRP increase. Values of 10 to 40 mg/L often coincide with mild inflammation like local bacterial infections, abscess, mild trauma, malignant tumors, most viral diseases etc. Up to 100 mg/L CRP indicate severe illness with inflammation that usually requires immediate medical treatment measures.
Values higher than 100 mg/L are found e.g. in bacterial sepsis or major surgical procedures.

SENSITIVITY AND SPECIFICITY

The Biopanda CRP Rapid Test has been evaluated with a leading commercial CRP ELISA test using clinical specimens. The results show that the sensitivity of the Biopanda CRP Rapid Test is 96.7% and the specificity is 98.5% relative to the leading ELISA test.

Method		ELISA		Total Results
Biopanda CRP Rapid Test	Results	Positive	Negative	
	Positive	29	3	32
	Negative	1	197	198
Total Results		30	200	230

Relative sensitivity: 96.7% (95%CI*: 82.8%~99.9%);
Relative specificity: 98.5% (95%CI*: 95.7%~99.7%);
Overall accuracy: 98.3% (95%CI*: 95.6%~99.5%). *Confidence Intervals

Precision

Cross-reactivity

The Biopanda CRP Rapid Test has been tested by anti-RF IgG,anti-MONOIgM, HBsAg, HBsAb, HBeAg, HBeAb, HBcAb, anti-syphilis IgG, anti-HIV IgG, anti-H.pylori IgG, anti-HAMA IgG, anti-CMV IgG, anti-CMV IgM,anti-Rubella IgG,anti-Rubella IgMand anti-Toxo IgG,anti-Toxo IgM positive specimens. The results showed no cross-reactivity.

Interfering Substances

The following potentially interfering substances were added to CRP negative and positive specimens.

Acetaminophen: 20 mg/dL
Acetylsalicylic Acid: 20 mg/dL
Ascorbic Acid: 20mg/dL
Creatin: 200 mg/dL
Bilirubin: 1,000mg/dL
Caffeine: 20 mg/dL
Gentisic Acid: 20 mg/dL
Albumin: 10,500mg/dL
Hemoglobin 1,000 mg/dL
Oxalic Acid: 600mg/dL
Cholesterol: 800mg/dL
Triglycerides: 1,600mg/dL
None of the substances at the concentration tested interfered in the assay.

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.

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

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Revision date: 10/01/2022