C-Reactive Protein Semi-Quantitative Rapid Test Device (Whole Blood/Serum/Plasma)

INTENDED USE

The C-Reactive Protein (CRP) is a marker of acute-phase response to inflammatory disorder. Clinical laboratory measurements have been used for many years in the management of a variety of clinical situations, such as bacterial infections, ischemic necrosis of tissue, and active inflammatory conditions. Recent studies show the marker is an indicator of future cardiovascular health and a predictor of cardiovascular mortality. Early identification of healthy subjects and of prognostic value in patients with acute coronary syndromes.1 As per the American Heart Association’s Cardiovascular Disease (CVD), CRP concentrations of 1-3 mg/L signify moderate risk and concentrations greater than 3 mg/L signify high risk for CVD. However, CRP level above 10 mg/L does not necessarily signify cardiac risk as it can be indicative of inflammation due to other factors. CRP concentration above 1 mg/L signifies low risk.

The CRP C-Reactive Protein Semi-Quantitative Rapid Test Device (Whole Blood/Serum/Plasma) utilizes a combination of colloidal gold conjugate and anti-CRP antibodies to detect CRP in whole blood, serum, or plasma. The minimum detection level of this test is 1 mg/L (T Line) with 2 reference lines representing values of 3 mg/L (R2) and 10 mg/L (R1).

PRINCIPLE

The C-Reactive Protein Semi-Quantitative Rapid Test Device (Whole Blood/Serum/Plasma) is a semi-quantitative, membrane-based immunoassay for the detection of CRP in whole blood, serum or plasma specimens. The test involves addition of the test specimen to the test device. 1 ml of buffer is added to the central well of the test device. The mixture migrates upward on the membrane by capillary action to react with anti-CRP antibodies on the membrane and generate a colored line. If the intensity of the test line (T) is weaker than reference line 1 (R1) but stronger than reference line 2 (R2), it indicates that the CRP level in the specimen is between 1-3 mg/L. If the intensity of the test line (T) is weaker than reference line 1 (R1), it indicates that the CRP level in the specimen is below 1 mg/L. If the intensity of the test line (T) is stronger than reference line 2 (R2), it indicates that the CRP level in the specimen is between 3-10 mg/L. For 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. If specimens are to be shipped, they should be packed in compliance with federal regulations covering the transportation of etiologic agents.

STORAGE AND STABILITY

Store as packaged in the sealed pouch at room temperature or refrigerated (2-8°C). The test is stable through the expiration date printed on the sealed pouch. The test device must remain in the sealed pouch until use. DO NOT FREEZE. Do not use beyond the expiration date.

SPECIMEN COLLECTION AND PREPARATION

1. Follow the instructions for use when collecting specimen. The CRP C-Reactive Protein Semi-Quantitative Rapid Test Device (Whole Blood/Serum/Plasma) can be performed using whole blood from venipuncture or fingertip, serum, or plasma specimens. To follow the Venipuncture Whole Blood Specimens: Collect anti-coagulated blood sample (EDTA, Specimens: 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. If specimens are to be shipped, they should be packed in compliance with federal regulations covering the transportation of etiologic agents.

MATERIALS

- Test devices
- Buffer
- Specimen collection containers
- Centrifuge (for plasma only)
- Timer

DIRECTIONS FOR USE

1. Place the test device on a clean and level surface. For Venipuncture or Fingertip Specimens: Hold the dropper vertically and transfer 1 drop of serum or plasma (approximately 40 µL) to the specimen well (S) of the test device, then add 1 drop of buffer (approximately 40 µL) and start the timer. See illustration below.

2. If migration is not observed in the result window after 30 seconds, add one or two extra drops of buffer. Do not use beyond the expiration date.

INTERPRETATION OF RESULTS

(Please refer to the illustrations in the first column of the table below)

<table>
<thead>
<tr>
<th>Result</th>
<th>Test Line (T) Intensity</th>
<th>Possible Interpretation of CRP Levels</th>
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</thead>
<tbody>
<tr>
<td><strong>POSI</strong></td>
<td>Three distinct red lines appear</td>
<td></td>
</tr>
<tr>
<td>Test Line (T) intensity is weaker than or close to R2</td>
<td>A Test Line intensity that is weaker than or close to R2 could be interpreted as a CRP level of 1-3 mg/L</td>
<td></td>
</tr>
<tr>
<td>Test Line (T) intensity is darker than R2, but lighter than or close to R1</td>
<td>A Test Line intensity that is darker than R2, but lighter than or close to R1, could be interpreted as a CRP level of 3-10 mg/L</td>
<td></td>
</tr>
<tr>
<td>Test Line (T) intensity is stronger than R1</td>
<td>A Test Line intensity that is stronger than R1 could be interpreted as a CRP level that is above 10 mg/L</td>
<td></td>
</tr>
<tr>
<td><strong>NEGAT</strong></td>
<td>Two red lines appear in R1 and R2 regions, and no apparent red or pink line appears in the test region (T)</td>
<td></td>
</tr>
<tr>
<td>No Test Line (T)</td>
<td>A No Test Line result could be interpreted as a CRP level that is below 1 mg/L</td>
<td></td>
</tr>
</tbody>
</table>

INTERVENTIONS

Test results are to be interpreted as follows:

- **POSITIVE**
  - A Test Line intensity that is weaker than or close to R2 could be interpreted as a CRP level of 1-3 mg/L |
  - A Test Line intensity that is darker than R2, but lighter than or close to R1, could be interpreted as a CRP level of 3-10 mg/L |
  - A Test Line intensity that is stronger than R1 could be interpreted as a CRP level that is above 10 mg/L |

- **NEGATIVE**
  - Two red lines appear in R1 and R2 regions, and no apparent red or pink line appears in the test region (T) |
  - A No Test Line result could be interpreted as a CRP level that is below 1 mg/L |

LIMITATIONS

1. The CRP C-Reactive Protein Semi-Quantitative Rapid Test Device (Whole Blood/Serum/Plasma) is the sole criteria for evaluating cardiac risks or inflammatory conditions.

2. The CRP C-Reactive Protein Semi-Quantitative Rapid Test Device (Whole Blood/Serum/Plasma) only will indicate the semi-quantitative level of CRP in the specimen and should not be used as the sole criteria for evaluating cardiac risks or inflammatory conditions.

3. If the event is positive results, further clinical evaluation should be considered with other clinical information available to the physician.

4. There is a slight possibility that some whole blood specimens with a very high viscosity or stored more than 2 days may not run properly on the test device; repeat the test with a serum or plasma specimen from the same patient using a new test device.

5. The elevated results of CRP in oral contraceptives (OC) users should be reported with caution as The American Physiological Society has recommended further studies on impact of OC use on CRP and inflammatory parameters.2

6. CRP values near the cut-off level (1 mg/L), reference line 1 (R1: 10 mg/L), and reference line 2 (R2: 3 mg/L) should be reported with caution as with all quantitative assays there exists some level of variation. Therefore, a T line with slightly higher intensity than R1 can also represent a value slightly below 10 mg/L. Similar observations may occur with values near 3 mg/L and 1 mg/L. A repeat test or further quantitative test is recommended in such cases.

*95% Confidence Interval

**Entirehipatns**

CRP is a non-specific marker for inflammation and cardiac risk marker. For ruling out cardiac risks, its expected value is less than 1 mg/L per AHA. A CRP level above 10 mg/L signifies some other source of inflammation and/or infection.

**SPECIMEN CHARACTERISTICS**

**EXCEPTION**

The CRP C-Reactive Protein Semi-Quantitative Rapid Test Device (Whole Blood/Serum/Plasma) has been tested in comparison with a leading commercial CRP EIA test using clinical specimens.

**INTERFERING SUBSTANCES**

DO NOT USE BEYOND THE EXPIRATION DATE.


**BIBLIOGRAPHY**

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Hangzhou Economic & Technological Development Area, Hangzhou, 310018, P.R.China

LONDON, W1G 9QR, U.K.

Ahon Biopharm (Hangzhou) Co., Ltd.

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1198 12th Street East, Hangzhou Economic & Technological Development Area, 310018, P.R.China

Number: 1155944042

Effective date: 2010-12-03