HS-CRP-W23

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

A rapid test for the semi-quantitative detection of C-Reactive Protein (CRP) in whole blood, serum or plasma specimens. For professional in vitro diagnostic use only.

INTENDED USE

The CRP C-Reactive Protein Semi-Quantitative Rapid Test Device (Whole Blood/Serum/Plasma) is a rapid chromatographic immunoassay for semi-quantitative detection of C-Reactive Protein in whole blood, serum or plasma specimens to aid in evaluating risks of cardiovascular disease.

SUMMARY

C-Reactive Protein (CRP) is a marker of acute phase response to inflammatory disorder. CRP 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.1

Recent studies suggest that CRP is a strong predictor of future coronary events in apparently healthy subjects and of prognostic value in patients with acute coronary syndromes.2 As per the American Heart Association (AHA) and Centers for Disease Control and Prevention (CDC), CRP concentrations of 1-3 mg/L signify moderate risk and concentrations greater than 3 mg/L signify high risk for CVD. CRP concentrations below 1 mg/L signify low risk.3.

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 selectively detect CRP in whole blood, serum or plasma. The Minimum Detection Level (MDL) of this test is 1 mg/L (T Line) with reference lines representing values of 3 mg/L (R).

PRINCIPLE

The CRP 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 membrane is pre-coated with anti-CRP antibodies on the test line region. During testing, specimen reacts with the particles coated with anti-CRP antibodies. 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 (R), it indicates that the CRP level in the specimen is between 1-3 mg/L. If the intensity of the test line (T) is stronger than reference line (R), it indicates that the CRP level in the specimen is above 3 mg/L. To serve as a procedural control, control line will always appear in control line region indicating that proper volume of specimen has been added and membrane wicking has occurred.

REAGENTS

The test device contains anti-CRP antibodies conjugated to colored particles and anti-CRP antibodies coated on the membrane.

PRECAUTIONS

- For professional *in vitro* diagnostic use only. Do not use it after expiration date.
- The test must remain in the sealed pouch until use.
- Do not eat, drink or smoke in the area where the specimens or kits are handled.
- Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout the procedure and follow the standard procedures for proper disposal of specimens.
- Wear protective clothing such as laboratory coats, disposable gloves or eye protection when specimens are being tested.
- Humidity and temperature can adversely affect results.
- The used test should be discarded according to local regulations.

STORAGE AND STABILITY

- Store as packaged in the sealed pouch at room temperature or refrigerated (2-30°C).
- The test device 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 it beyond the expiration date.

SPECIMEN COLLECTION AND PREPARATION

● Preparation

Before performing the test, please make sure that all components are brought to room temperature (see storage). Take a vial with buffer solution out of the kit. Mark with patients name or ID. Open the screw cap.

● Blood Sample Taking

1) Disinfect the finger tip. Use lancet device extract a drop of blood from the finger tip;
2) With the supplied capillary, take a volume of 10μl from the blood drop. It is important that the end-to-end capillary is filled until the upper end. Due to hygienic reasons, hold the capillary with a capillary holder or tweezers. Alternatively, the blood can also be taken with a micro pipette. **Please note: In case of using micro pipettes or other capillaries a sample volume of exactly 10μl must be administered.**
   Please dilute the blood sample immediately to avoid clotting.

● Sample Dilution / Sample Stability

3) Administer the blood-filled end-to-end capillary into the accordingly plastic vial with dilution buffer. Alternatively, the 10μl of blood can be added directly with the micro pipette into the buffer. **OR** transfer 5μl serum/plasma into the accordingly plastic vial with dilution buffer.
4) Close the vial and shake the sample by hand forcefully for approximately 10 seconds so that the blood is released from the capillary and sample and dilution buffer mix themselves well.
5) Let the diluted sample rest for approximately 1 minute.
6) The sample can then be used immediately or stored for up to 8 hours.

NOTE

EDTA-, citrate-or heparin-blood can be used as well. Before performing the test, it has to be diluted accordingly with the supplied buffer.

MATERIALS

Materials Provided

- Individually pouched test Device
- End-to-end capillary (10μl)
- Plastic vial with buffer
- Package insert
- Dropper

Materials Required but Not provided

- Lancet
- Capillary holder
- Timer

DIRECTIONS FOR USE

Allow test device, specimen, buffer and/or controls to equilibrate to room temperature (15-30°C) prior to testing.

1. Bring the pouch and buffer to room temperature before opening it. Remove the test device from the sealed pouch and use it as soon as possible. Best results will be obtained if the test is performed immediately after opening the foil pouch.
2. Open the vial with the diluted sample and Hold the dropper vertically and transfer 3 drop of diluted sample (approximately 75 μL) to the specimen well (S) of the test device and start the timer.
3. Wait for the red line(s) to appear. Read the results at 5 minutes. Do not interpret the result after 7 minutes.

INTERPRETATION OF RESULTS

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

Result	Test Line (T) Intensity	Possible Interpretation of CRP Levels
POSITIVE	Three distinct red lines appear.	
	Test Line (T) intensity is weaker than or close to reference line (R)	A Test Line intensity that is weaker than or close to R could be interpreted as a CRP level of 1-3 mg/L.
	The intensity of the test line (T) is darker than the reference line (R)	A Test Line intensity that is darker than R, , could be interpreted as a CRP level of over 3 mg/L.
NEGATIVE	Two red lines appear in C and R regions, and no apparent red or pink line appears in the test region (T).	
	No Test Line (T)	A No Test Line result could be interpreted as a CRP level that is below 1 mg/L.
INVALID		
	Control line fail(s) to appear. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for failure of reference lines to develop. Review the procedure and repeat the test with a new test device. If the problem persists, discontinue using the test kit immediately and contact your local distributor.	
		

LIMITATIONS

1. The C-Reactive Protein Semi-Quantitative Rapid Test Device (Whole Blood/Serum/ Plasma) is for in vitro diagnostic use only. This test should be used for the detection of CRP in whole blood, serum or plasma specimen.
2. The C-Reactive Protein Semi-Quantitative Rapid Test Device (Whole Blood/Serum/ Plasma) will only 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. Even if the test results are positive, 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 contraceptive (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.[4]
6. CRP values near the cut-off level (1 mg/L), reference level 2 (R: 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 C 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/further quantitative test is recommended in such cases.
7. 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.

EXPECTED VALUES

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

PERFORMANCE CHARACTERISTICS

Accuracy

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.

Method		EIA		
		Positive		Negative
CRP Rapid Test Device	Ranges	1-3 mg/L	≥3 mg/L	0-1 mg/L
	0-1 mg/L	3	1	347
	1-3 mg/L	79	9	13
	≥3 mg/L	8	110	0
Total Results		90	120	360
% Agreement		87.8%	91.7%	96.4%
		90.0%		

Precision

Intra-Assay

Within-run precision has been determined by using replicates of 10 tests for each of three lots using CRP specimen levels at 1 mg/L, 3 mg/L, 10 mg/L. The specimens were correctly identified >98% of the time.

Inter-Assay

Between-run precision has been determined by using CRP specimen levels at 1 mg/L, 3 mg/L, 10 mg/L of CRP in 10 independent assays. Three different lots of the CRP C-Reactive Protein Semi-Quantitative Rapid Test Device (Whole Blood/Serum/Plasma) have been tested using these specimens. The specimens were correctly identified >98% of the time.

Interfering Substances

The following substances do not interfere with the test results at the indicated concentrations: human albumin at 110 mg/mL, bilirubin at 6 mg/mL, hemoglobin at 10 mg/mL, cholesterol at 5 mg/mL and triglycerides at 15 mg/mL.

BIBLIOGRAPHY

1. Thompson D, Milford-Ward A, Whicher JT. The value of acute phase protein measurements in clinical practice. *Ann. Clin Biochem*; 29:123–31 (1992).
2. Rifai N, Ridker PM. High-Sensitivity C-reactive protein: A Novel and Promising Marker of Coronary Heart Disease. *Clinical Chemistry* 47:3 403–411 (2001).
3. Pearson TA, et.al. Markers of Inflammation and Cardiovascular Disease: Application to Clinical and Public Health Practice: A Statement for Healthcare Professionals From the Centers for Disease Control and Prevention and the American Heart Association, Circulation (2003); 107; 499-511.
4. Dreon DM, Slavin JL; and Phinney, SD. Oral Contraceptives Increase C-Reactive Protein, An Inflammatory Biomarker by The American Physiological Society, April 9 (2003).

GLOSSARY OF SYMBOLS

ρ	Catalog number	0	Temperature limitation
ι	Consult instructions for use	Λ	Batch code
I	In vitro diagnostic medical device	ε	Use by
μ	Manufacturer	T	Contains sufficient for <n> tests
σ	Do not reuse	A	Authorized representative in the European Community
Y	CE marking according to IVD Medical Devices Directive 98/79/EC		

μ

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