Hs – CRP Device (2-30°C)

CATALOGUE NUMBER	KIT SIZE (TESTS)
RADCRP1	20 Tests

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).

Test 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.

Materials Provided
Test devices
Buffer
Disposable specimen pipettes
Package Insert

Materials not provided: Timer, Specimen collection container, Lancets (for fingerstick whole blood only), Centrifuge (for plasma only)

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.

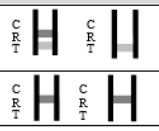
Reagent Preparation and Stability:
Store as packaged in the sealed pouch at room temperature or refrigerated (2-30°C). The test device is stable through the expiration date printed on the sealed pouch. The test device must remain in the sealed pouch until use. **DO NOT FREEZE.** Do not use it beyond the expiration date.

Specimen Collection and Storage:
- The CRP C-Reactive Protein Semi-Quantitative Rapid Test Device (Whole Blood/Serum/ Plasma) can be performed using whole blood (from venipuncture or fingerstick), serum, or plasma specimens.
- To collect Venipuncture Whole Blood Specimens: Collect anti-coagulated blood sample (EDTA, Heparin, and Sodium Oxalate) following standard laboratory procedures.
- Separate serum or plasma from blood as soon as possible to avoid hemolysis. Use only clear, non-hemolyzed specimens.
- Testing should be performed immediately after specimen collection. Do not leave the 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 run within 2 days of collection. Do not freeze whole blood specimens. Whole blood collected by fingerstick should be tested immediately.
- 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.

Assay Procedure:

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. Transfer 2 drops of serum or plasma (approximately 50 µL) to the specimen well of the device with the provided disposable pipette, and then start the timer.
   OR
   Transfer 3 drops of whole blood specimen (approximately 75 µL) to the specimen well of the device with the provided disposable pipette, then add 1 drop of buffer and start the timer.
   OR
   Allow 3 hanging drops of fingerstick whole blood specimen to fall into the center of the specimen well (S) on the device, then add 1 drop of buffer and start the timer.
   Avoid trapping air bubbles in the specimen well (S), and do not add any solution to the result area.
   As the test begins to work, color will migrate across the membrane.
3. The result should be read at 5 minutes. Do not interpret the result after 10 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 of the assay:
1. The CRP 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 CRP 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.

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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.

References:

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).

REF	Catalog number		Temperature limitation
	Consult instructions for use	LOT	Batch code
IVD	*In vitro* diagnostic medical device		Use by
	Manufacturer		

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