CRP Semi-Quantitative Rapid Test Cassette (Whole Blood /Serum/Plasma)

Package Insert

REF CCR-T402 | English

A rapid test for the diagnosis of inflammatory conditions to detect CRP Semi-quantitatively in whole blood, serum or plasma.
For professional in vitro diagnostic use only.

【INTENDED USE】

The CRP Semi-Quantitative Rapid Test Cassette (Whole Blood/Serum/Plasma) is a rapid chromatographic immunoassay for the Semi-quantitative detection of human CRP in whole blood, serum or plasma as an aid in the diagnosis of inflammatory conditions.

【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 CRP Semi-Quantitative Rapid Test Cassette (Whole Blood/Serum/Plasma) detects C-reactive Protein through visual interpretation of color development on the internal strip. Anti-CRP antibodies are immobilized on the test region of the membrane. During testing, the specimen reacts with anti-CRP antibodies conjugated to colored particles and precoated on the sample pad of the test. The mixture then migrates through the membrane by capillary action, and interacts with reagents on the membrane. If the intensity of the test band is weaker than reference band (R), it indicates that the CRP level in the specimen is between 10-30 mg/L. If the intensity of the test band (T) is stronger than the reference band (R), it indicates that the CRP level is above 30 mg/L. The appearance of control line serves as a procedural control, indicating that the proper volume of specimen has been added and membrane wicking has occurred.

【REAGENTS】

The test strips include anti-CRP antibody coated particles and anti-CRP antibody coated on the membrane.

【PRECAUTIONS】

- 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.

【STORAGE AND STABILITY】

- The kit should be stored at 2-30°C until the expiry date printed on the sealed pouch.
- The test must remain in the sealed pouch until use.
- **Do not freeze.**
- 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.

【MATERIALS】

Material Provided

- Test Cassettes
- Droppers
- Capillaries
- Single Dilution Buffer Vials
- Package Insert

Materials required but not provided

- Specimen collection tubes
- Timer
- Centrifuge

【SPECIMEN COLLECTION AND PREPARATION】

Preparation

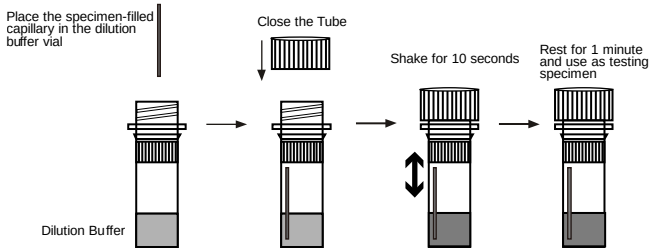
1. Before performing the test, please make sure that all components are brought to room temperature(15-30 ℃). Cold buffer solution or moisture condensation on the membrane can lead to invalid test results.
2. Take a dilution buffer vial out of the kit. Label it with patient's ID. Open the screw cap.

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

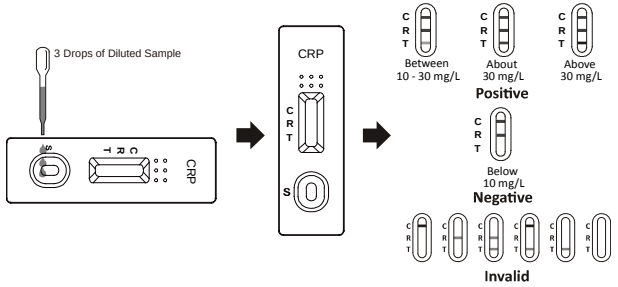
1. With the capillary, aspirate 10μL blood. It is important that the capillary is filled end to end to ensure 10μL blood.
2. Place the end-to-end blood-filled capillary into the dilution buffer vial. Alternatively, the 10 μL of specimen can be added directly with the micro pipette into the dilution buffer vial.
3. Close the vial and shake the sample vigorously for approximately 10 seconds so that sample and dilution buffer mix well. (See Figure-1)
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. Specimens containing EDTA, citrate or heparin can also be used.



【DIRECTIONS FOR USE】

Bring tests, specimens, buffer, and/or controls to room temperature (15-30°C) before use.

1. Remove the Test Cassette from the sealed pouch, and place it on a clean, level surface. Label the device with patient or control identification. For best results, the assay should be performed within one hour.
2. Open the vial containing specimen. Transfer 3 drops of the specimen to the sample well. Start the timer.
3. Wait for the colored lines to appear. The result should be read at 5 minutes. Do not interpret the result after 10 minutes.



【INTERPRETATION OF RESULTS】

POSITIVE: Three colored bands appear on the membrane. Two bands appear in Control region (C) and Reference region (R) respectively, and another band should appear in the test region (T).

- A test band (T) signal which is weaker than the R indicates a CRP level **between 10 and 30 mg/L**.
- A test band (T) signal which is close to R indicates a CRP level **about 30mg/L**.
- A test band (T) signal which is stronger than the R indicates a CRP level **above 30 mg/L**.

NEGATIVE: Color lines appear in both the control (C) and reference (R) regions No colored line appears in the test line region (T). It indicates a CRP level less than 10 mg/L.

INVALID: C band or Reference band fail to appear. Results from any test unit, which has not produced C band or R band at the specified read time must be discarded. Please review the procedure and repeat with a new test. If the problem persists, discontinue using the kit immediately and contact your local distributor.

NOTE:

1. The color intensity in the test region (T) may vary depending on the concentration of CRP present in the specimen. Therefore, any shade of color in the test region should be considered positive. Please note that this is a semi-quantitative test only, and cannot determine the concentration of CRP in the specimen.
2. Insufficient specimen volume, incorrect operating procedure or expired tests are the most likely reasons for control band failure.

【QUALITY CONTROL】

Internal procedural controls are included in the test. Control brand and reference band appearing in the reference regions are considered internal procedural controls, confirming sufficient specimen volume and correct procedural technique.

External controls are not supplied with this kit. It is recommended that positive and negative controls be tested as a good laboratory practice to confirm the test procedure and to verify proper test performance.

【LIMITATIONS】

1. The CRP Semi-Quantitative Rapid Test Cassette (Whole Blood/Serum/Plasma) is for professional in *vitro diagnostic* use, and should only be used for the semi-quantitative detection of C - reactive protein.
2. The CRP Semi-Quantitative Rapid Test Cassette (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 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. CRP values near the cut-off level (10 mg/L) and reference line (R: 30 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 R can also represent a value slightly below 30 mg/L. A repeat test or further quantitative test is recommended in such cases.
5. 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.

【PERFORMANCE CHARACTERISTICS】

Sensitivity and Specificity

The CRP Semi-Quantitative Rapid Test Cassette (Whole Blood/Serum/Plasma) has been evaluated with a leading commercial CrP EIA test using clinical specimens. The results show that the sensitivity of the CRP Semi-Quantitative Rapid Test Cassette (Whole Blood/Serum/Plasma) is >98.8% and the specificity is 98.7% relative to the leading EIA test.

Method		EIA		Total Result
CRP Semi-Quantitative Rapid Test Cassette (Whole Blood /Serum /Plasma)	Results	Positive	Negative	
	Positive	79	4	83
	Negative	1	296	297
Total Result		80	300	380

Relative sensitivity: 79/80=>98.8% (95%CI*: 95.6%~100%);
Relative specificity: 296/300=98.7% (95%CI*: 96.6%~99.6%);
Accuracy: (79+296)/(79+1+4+296)=98.7%(95%CI*: 97.0%~99.6%). *Confidence Intervals

Precision

Cross-reactivity

The CRP Semi-Quantitative Rapid Test Cassette (Whole Blood/Serum/Plasma) has been tested with Rheumatoid Factor, HAMA,, HBsAg, HBsAb, HBeAg, HBeAb, HBcAb, syphilis, anti-HIV, anti-H.pylori, MONO, anti-CMV, anti-Rubella and anti-Toxoplasmosis 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
Cholesterol: 800mg/dL
Caffeine: 20 mg/dL
Gentisic Acid: 20 mg/dL
Albumin: 10,500mg/dL
Hemoglobin 1,000 mg/dL
Oxalic Acid: 600mg/dL
Triglycerides: 1,600mg/dL

None of the substances at the concentration tested interfered in the assay.

【BIBLIOGRAPHY】

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

	Attention, see instructions for use	Σ	Tests per kit	EC REP	Authorized Representative
IVD	For in vitro diagnostic use only		Use by		Do not reuse
2°C 30°C	Store between 2-30°C	LOT	Lot Number	REF	Catalog #
	Do not use if package is damaged				

Hangzhou AllTest Biotech Co., Ltd.
#550, Yinhai Street
Hangzhou Economic & Technological Development Area
Hangzhou - 310018, P. R. China
www.alltests.com.cn

EC REP
MedNet GmbH
Borkstrasse 10
48163 Muenster
Germany

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