CRP Rapid Test Cassette (Whole Blood/Serum/Plasma) Package Insert

REF CCR-402	English

A rapid test for the diagnosis of inflammatory condition by detecting CRP qualitatively in human whole blood, serum or plasma. For professional in vitro diagnostic use only.

INTENDED USE

The CRP Rapid Test Cassette (Whole Blood/Serum/Plasma) is a rapid chromatographic immunoassay for the qualitative detection of human CRP in whole blood, serum or plasma as an aid in the diagnosis of inflammatory condition. The cutoff of the test is 10 μg/mL.

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.[1] There is a strong correlation between serum levels of CRP and the onset of the inflammatory process.[2] Monitoring the levels of CRP in patient's sera indicates the effectiveness of treatment and the assessment of patient recovery.[3] It is used in particular to differentiate bacterial infections from virus infections.

PRINCIPLE

The CRP Rapid Test Cassette (Whole Blood/Serum/Plasma) detects C-reactive Protein through visual interpretation of color development on the internal cassette. The sample now moves through the test cassette from bottom to top. If the test sample contains CRP, it attaches to the CRP antibody which is conjugated with a red gold colloidal for color marking. The more CRP is contained in the sample, the more red lines become visible.

A red line should always appear in the control (C) line area. It serves as a procedural control, confirming that sufficient specimen volume was used and indicates an adequate membrane wicking and proper procedural technique.

REAGENTS

The test cassettes include CRP antibody coated particles and 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.

SPECIMEN COLLECTION AND PREPARATION

Preparation

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.

1. Take a tube with buffer solution out of the kit. Document name or ID on it. Open the screw cap.

Blood Sample Taking

2. Collect the specimen according to standard procedures.
   - 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.
   - 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.
   - EDTA K2, Heparin sodium, Citrate sodium and Oxalate potassium can be used as the coagulant tube for collecting the blood specimen.

Sample Dilution / Sample Stability

3. Administer the blood-filled end-to-end capillary into the plastic tube with dilution buffer. Alternatively, the **10 μL of specimen** can be added directly with the micro pipette into the buffer
4. Close the tube and shake the sample by hand forcefully for approximately 10 seconds so sample and dilution buffer mix 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.

MATERIALS

Material Provided

- Test cassettes
- Plastic tubes with buffer
- Capillaries
- Package Insert
- Droppers

Material Required But Not Provided

- Timer
- Centrifuge

DIRECTIONS FOR USE

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

1. Remove the Test Cassette from its sealed pouch, and place it on a clean, level surface. For best results, the assay should be performed within one hour.
2. Open the tube with the diluted sample. Transfer **3 drops (** approximately 120μL **)** of mixed specimens to 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 results at 10 minutes.

INTERPRETATION OF RESULTS

(Please refer to the illustration above)

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

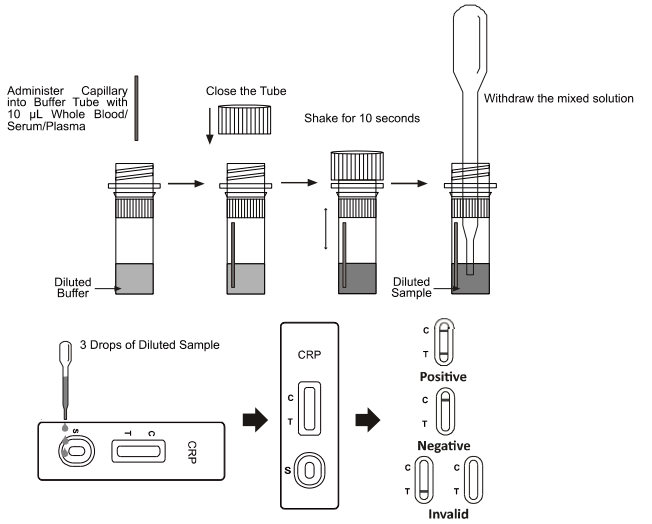
***NOTE:** The intensity of the color in the test line region (T) will vary depending on the concentration of CRP antigen present in the specimen. Therefore, any shade of color in the test line region (T) should be considered positive.

NEGATIVE: One colored 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.

NOTE:

1. The intensity of the color in the test region (T) may vary depending on the concentration of analytes 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 analytes in the specimen.
2. Insufficient specimen volume, incorrect operating procedure or expired tests are the most likely reasons for control line failure.



QUALITY CONTROL

- Internal procedural controls are included in the test. Control line appearing in the control regions is considered an internal quality procedural control, 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 Rapid Test Cassette (Whole Blood/Serum/Plasma) is for professional *in vitro* diagnostic use, and should only be used for the qualitative detection of C - reactive protein.
2. The CRP Rapid Test Cassette (Whole Blood/Serum/Plasma) will only indicate the presence of CRP antigen 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 2000 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 like 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 μg/mL often coincide with mild inflammation like local bacterial infections, abscess, mild trauma, malignant tumors, most viral diseases etc. Up to 100 μg/mL CRP indicate severe illness with inflammation that usually requires immediate medical treatment measures.

Values higher than 100 μg/mL are found e.g. in bacterial sepsis or major surgical procedures.

PERFORMANCE CHARACTERISTICS

Sensitivity and Specificity

The CRP Rapid Test Cassette (Whole Blood/Serum/Plasma) has been evaluated with a leading commercial CRP ELISA test using clinical specimens. The results show that the sensitivity of the CRP Rapid Test Cassette (Whole Blood/Serum/Plasma) is 96.7% and the specificity is 98.5% relative to the leading ELISA test.

Method		ELISA		Total Result
CRP Rapid Test Cassette (Whole Blood /Serum /Plasma)	Results	Positive	Negative	
	Positive	29	3	32
	Negative	1	197	198
Total Result		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

Cross-reactivity

The CRP Rapid Test Cassette (Whole Blood/Serum/Plasma) has been tested by anti-RF IgG, anti-MONO IgM, 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 IgM and 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	Caffeine: 20 mg/dL
Acetylsalicylic Acid: 20 mg/dL	Gentisic Acid: 20 mg/dL
Ascorbic Acid: 20mg/mL	Albumin: 10,500 mg/dL
Creatine: 200 mg/dL	Hemoglobin 1,000 mg/dL
Bilirubin: 1,000 mg/dL	Oxalic Acid: 600 mg/dL
Cholesterol: 800 mg/dL	Triglycerides: 1,600 mg/dL

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

LITERATURE 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.

Index of Symbols

	Consult instructions for use or consult electronic instructions for use		Contains sufficient for <n> tests	2°C 30°C	Temperature limit
IVD	*In vitro* diagnostic medical device	LOT	Batch code	REF	Catalogue number
EC REP	Authorized representative in the European Community		Use-by date		Do not re-use
	Do not use if package is damaged and consult instructions for use		Manufacturer		

ACRO BIOTECH, Inc.
4650 Arrow Highway,
Suite D-6 Montclair, CA 91763, U.S.A.
Tel: +1 (909) 541-5085 www.acrobiotech.com

EC REP
MedNet EC-REP GmbH
Borkstrasse 10
48163 Muenster
Germany

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