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

REF CCR-U402
English

A rapid test for the diagnosis of inflammatory condition by detecting 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 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. 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 virus 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. The sample now moves through the test strip from bottom to top. If the test sample contains CRP, it attaches to the first anti-CRP antibody which is conjugated with a red gold colloidal for color marking. The red CRP-antibody-gold complex, together with the sample liquid, diffuses through the membrane that is pre-dispensed with lines of different amounts of the second anti-antibody. The CRP-antibody-gold complex is immobilized by the second antibodies leading to the formation of red lines. The number of lines depends on the concentration in the sample. 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 strips include anti-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 patients 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-, citrate- or heparin blood can be used as well. Before performing the test, it has to be diluted accordingly with the supplied buffer.

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

- Cassettes
- Plastic tubes with buffer
- Droppers
- Alcohol Pads
- Capillary Tubes
- Package Insert
- Sterile Lancets

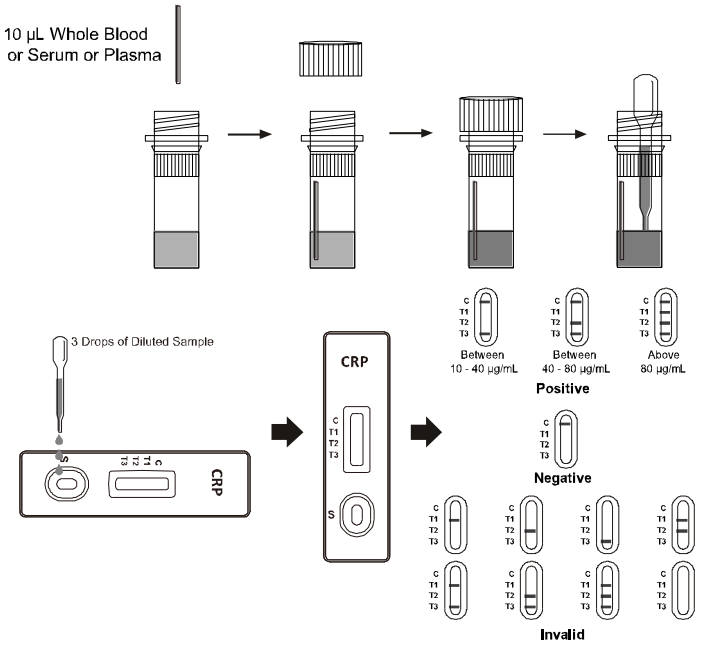
Material Required But Not Provided

- Timer
- Centrifuge

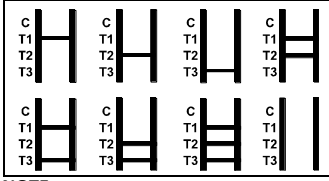
DIRECTIONS FOR USE

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** of (approx. 120μL) 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

POSITIVE RESULT:	Possible Interpretation of CRP Levels
	• A Control line (C) and a test line (T3) appears indicates a CRP level of 10 μg/mL at least.
	• A Control line (C) and two test lines (T3 and T2) appear indicates a CRP level of 40 μg/mL at least.
	• A Control line (C) and three test lines (T1, T2 and T3) appears indicates a CRP level of 80 μg/mL at least.
NEGATIVE RESULT:	
	Only a Control line (C) appears and no colored line appears in the test region (T) indicates a CRP level is lower than 10 μg/mL.
INVALID RESULT:	
	No Control line appears. Results from any test which has not produced Control line 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 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 positive 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 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. 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 >99.9% and the specificity is 97.5% relative to the leading EIA test.

Method		EIA		Total Results
CRP Semi-Quantitative Rapid Test Cassette (WB/S/P)	Results	Positive	Negative	
	Positive	67	12	79
	Negative	0	473	473
Total Results		67	485	552

Relative Sensitivity: >99.9% (95%CI*: 94.6%~100%)
Relative Specificity: 97.5% (95%CI*: 95.7%~98.7%)
Accuracy: 97.8% (95%CI*: 96.2%~98.9%) *Confidence Intervals

Precision

Cross-reactivity

The CRP Semi-Quantitative Rapid Test Cassette (Whole Blood/Serum/Plasma) has been tested by 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

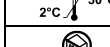
The following potentially interfering substances were added to CRP negative and positive specimens.

Acetaminophen: 20 mg/dL
Acetylsalicylic Acid: 20 mg/dL
Ascorbic Acid: 20mg/dL
Creatin: 200 mg/dL
Bilirubin: 1,000 mg/dL
Cholesterol: 800 mg/dL
Caffeine: 20 mg/dL
Gentisic Acid: 20 mg/dL
Albumin: 10,500 mg/dL
Hemoglobin: 1,000 mg/dL
Oxalic Acid: 600 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.

	Caution
	For *in vitro* diagnostic use only
	Store between 2-30°C
	Do not use if package is damaged
	Authorized representative in EU
	Catalog #
	Tests per kit
	Use by
	Lot number
	Manufacturer
	Do not reuse
	Consult instructions for use
	Importer
	Distributor


Manufacturer

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