# Rapid Response®
## CRP Test Strip (Quad Line)
**(Whole blood/Serum/Plasma)**

REF CRP4-13S20, CRP4-13S40 Product Insert

*For professional in vitro diagnostic use only.*

## Intended Use

The Rapid Response® CRP Test Strip (Quad Line) (Whole Blood/Serum/Plasma) is used for semi-quantitative determination and monitoring of CRP concentrations in whole blood/serum/plasma specimens.

## Introduction

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 Rapid Response® CRP Test Strip (Quad Line) is an immunochromatographic test, based on two specific antibodies against human CRP. The concentration-dependent formation of test lines allows a rapid semiquantitative determination of CRP in whole blood samples.
The tip of the test strip is dipped into the test sample which is diluted with buffer solution. The sample then 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-CRP antibody. The CRP-antibody-gold complex is immobilized by the antibodies coated on the membrane leading to the formation of red lines. The number of lines depends on the CRP concentration in the sample. The more CRP is contained in the sample, the more red lines become visible.
The control line serves as a procedural control and indicates that sufficient volume of specimen has been added and membrane wicking has occurred.

## Materials

### Materials Provided

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

### Materials Required but Not Provided

- Lancet
- Capillary holder
- Timer

## 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 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 according to 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 Storage

### 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

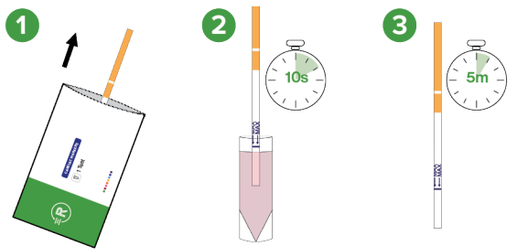
1. Disinfect the finger tip. Use lancet device extract a drop of blood from the finger tip:
2. With the supplied capillary, take a volume of 10 µl from the blood drop. It is important that the end-to-end capillary is filled until the upper end. Due to hygienic reasons, hold the capillary with a capillary 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 10 µl must be administered.**
**Please dilute the blood sample immediately to avoid clotting.**

### Sample Dilution / Sample Stability

3.
a. Administer the blood-filled end-to-end capillary into plastic vial with dilution buffer. **OR**
b. Alternatively, the 10µl of blood can be added directly with the micro pipette into the buffer. **OR**
c. Transfer 5µl serum/plasma into the plastic vial with dilution buffer.
4. Close the vial and shake the sample by hand forcefully for approximately 10 seconds blood sample and dilution buffer mix are thoroughly mixed.
5. Let the diluted sample rest for approximately 1 minute.

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. If using these samples it must also be diluted with the supplied buffer.

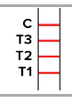
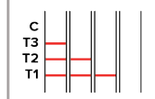
## Test Procedure




1. Open the aluminum cover and take out the test strip holding it by the solid colored end. **Do not touch the white result field with your fingers. After opening the aluminum pouch, the tests should be performed immediately as the test is sensitive to humidity.**
2. Open the vial with the diluted sample and dip the opposing end of the strip into the liquid. Ensure you do not submerge the test strip beyond the maximum line (MAX). Do not submerge the white membrane of the strip (results area). Hold the test strip in the buffer for a minimum of 10 seconds.
3. Remove the test strip from the sample and place it on a non-absorbent surface (e.g. the test pouch). Alternatively, the test strip can remain in the tube. Start a timer for 5 minutes.
4. Wait for the appearance of colored lines. Read the result after 5 minutes. **Please note that the test must be read after exactly 5 minutes to ensure correct semiquantitative results**. Interpret the results according to the chart below. To interpret the results please look at the line pattern that has formed in the white membrane field of the strip.

## Result Interpretation

The cut-off of detection of the test is 10 µg/ml.

| Result | Test Line Intensity | Possible Interpretation of CRP Levels |
|---|---|---|
| **POSITIVE** | More than one line (control line C) appears | |
|   | 1 red test line (T1) and 1 red control line (C) | AT CRP concentrations of approximately 10 µg/ml and higher a test line that is faint in the beginning appears in the lower area in addition to the control line. |
|   | 2 red test lines (T1 and T2) and 1 red control line (C) | Approximately 40 µg/ml on a second faint colored test line appears above the first test line. |
|   | 3 red test lines (T1, T2 and T3) and 1 red control line (C) | Approximately 80 µg/ml on a third faint test line appears above the first two test lines. |
| **NEGATIVE** | Only the red control line appears | |
|   | No Test Line (T) | A No Test Line result could be interpreted as a CRP level that is below 10 mg/L. |
| **INVALID** | | |
|   | NA | 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. |

**NOTE:**
1. Please read the test only once after 5 minutes. It is quite natural for immunochromatography and the kinetics of rapid tests, that the intensity of all lines increases over time. If the test is read later, an accurate semiquantitative interpretation of the test result is not ensured any more, as low concentrations would be estimated too high.

## QUALITY CONTROL

- Internal procedural controls are included in the test. A colored band appearing in the control region (C) 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 OF THE TEST

- CRP is not a specific marker for a certain disease. As with all in vitro diagnostics, the result should not be interpreted on its own but must be correlated with clinical findings. Often, CRP increase occurs before the symptoms become apparent, therefore temporal connections should be considered as well.
- Intraindividual variation of CRP values is relatively high. In general, values > 10 µg/ml can be regarded as elevated in the majority of the patients.
- The test is not suitable for risk stratification of coronary heart diseases. For this, it is not sensitive enough.

## PERFORMANCE

- The test was calibrated against the international human CRP reference standard of the WHO 85/506. The detection limit of the Rapid Response® CRP Test is adjusted to 10 µg/ml
- In such a way that a concentration of 10 µg/ml in the undiluted specimen material after dilution with the supplied buffer yields a positive red line.
- If the undiluted specimen contains more than 40 µg/ml CRP, a second red line appears. With concentrations higher than 80 µg/ml

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CRP, a third red line appears.

- These concentration ranges could be confirmed in comparison to a quantitative reference test.
- Hook effects could not be proven up to a concentration of 2000 µg/ml CRP. At this concentration, the test indicated results of >80 µg/ml.

## 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.


## Glossary of Symbols

| | | |
|---|---|---|
| Consult instructions for use | Test per Kit | Catalogue # |
| Store between 2°C to 30°C | Use by | Do Not Reuse |
| Lot Number | Tests per kit | Manufacturer |
| For *in vitro* diagnostic use only | | |


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