Instruction for use

QuickSens® CRP

Rapid test for the determination of C-reactive protein (CRP) in whole blood, plasma or serum
Reference no.: LF01002

Application

QuickSens® CRP is an immuno-chromatographic rapid test for the semi-quantitative determination of CRP in whole blood, plasma or serum. With the QuickSens® Ω100 optoelectronic reader (optional) it is possible to perform an exact quantification. QuickSens® CRP is a reliable test to confirm or exclude the presence of bacterial inflammations as the CRP level is markedly elevated in the presence of chronic systemic inflammations. Values up to 10.0 mg/l considered to be normal for adults. People with a CRP concentration above 10.0 mg/l often suffer from a minor or local inflammation, whereas values above 50.0 mg/l are often concomitant with a severe inflammation while values above 100.0 mg/l indicate severe diseases, bacterial infections (sepsis), bacterial meningitis or pneumonia, pancreatitis, severe post-operative wounds, active rheumatic diseases, active Crohn's disease or certain large tumors.

The C-reactive protein is synthesized in the liver in cases of bacterial infection or tissue damage. CRP belongs to the Pentraxin group and is made up of five non-covalently bound sub-units which form the protein-complex with a molecular weight of 105 kDa.
Within the Pentraxin group, CRP takes an exceptional position because its concentration increases unusually fast after numerous inflammatory reactions and tissue lesions.
Therefore, it serves as a marker for the “acute phase reaction”. Certain plasma proteins are synthesized within 6-48 h after the onset of either an infection or an acute tissue lesion (“acute phase reaction”). CRP is then synthesized as a response to the release of cytokines into the bloodstream by activated leukocytes.

Indications

CRP is the most important unspecific inflammatory parameter. Typical indications are: e.g. suspected appendicitis, cholecystitis, acute respiratory disease, diverticulitis, infection of the urinary tract, rheumatic and many other inflammatory diseases.

The CRP value may be elevated at a very early stage of the infection, i.e. before the onset of fever and when the leukocyte number is still inconspicuous. In contrast to the results obtained from measurements of erythrocyte sedimentation, the concentration of CRP will rapidly decline to normal after the inflammation has disappeared. Being an acute phase parameter, CRP is capable of distinguishing an acute course from a chronic course of a disease: In contrast to a chronic medical status, acute status causes a stronger increase of the CRP concentration which is usually proportional to the magnitude of the inflammation.

Moreover, the CRP value can be used in order to:

- Monitor severe infections, e.g. postoperative ones, infections due to exacerbations of chronic diseases or those resulting from an infection of the amniotic fluid due to early amniorrhexis.
- Distinguish viral from bacterial infections, provided that the latter does not occur too localized: Viral infections either lead to a very slight increase of the CRP concentration or no increase at all.
- Confirm (or refute) the success of an antibacterial or anti-inflammatory therapy at a very early stage as the decline in CRP concentration often precedes the clinical symptoms. In this context, a decreasing/increasing inflammatory reaction can be monitored by a decreasing/increasing level of CRP with a delay of 24 h only.

Principle of the test

The test contains two different specific monoclonal antibodies for CRP, one of which is gold-labelled. Both antibodies specifically bind to two different regions of CRP. If the sample matrix contains CRP, an anti-CRP-antibody (gold-labelled) ↔ CRP ↔ anti-CRP-antibody sandwich will be formed as follows: first, the sample fluid releases the gold-labelled anti-CRP-antibody from its matrix within the test strip. CRP then forms an intermediary complex with this antibody, which then moves diffusively along the test strip. At the position marked “T” there is the second type of antibody which forms a sandwich together with the intermediary complex. Depending on the concentration of CRP in the sample a red/purple line becomes visible at the “T”- marking, hence the intensity of the test line increases proportionally to the concentration of CRP.
If the sample does not contain CRP, no complex can be formed and therefore no test line will appear. The excess gold-labelled antibodies bind unspecific to the control line (“C”) and indicate that the test has worked properly.

Contents of package

25 disposable QuickSens® CRP tests
25 tubes with dilution buffer
1 instruction for use
1 lot-specific reference card (optional)

Additional material required

- Blood sample vessel with heparin or citrate as anticoagulant or a vessel designed for obtaining serum
- Timer
- Sterile lancets or finger prickers
- Laboratory pipette and pipette tips
- Optional: QuickSens® Ω100 optoelectronic reader, if quantification is required

Precautions and hazards

1. For professional use only.
2. Prior to performing the test, carefully read the instruction for use and follow it exactly.
3. The test must be at room temperature when used.
4. Do not use the test beyond the expiry date.
5. Use exact sample volume specified in the section “Sample material”.
6. Occasionally, the dilution buffer will show a color change into yellow. However, this has no influence on the test result.
7. Avoid touching the test area and do not apply any liquid other than into the sample reservoir (“S”).
8. Do not press on the cassette while the test is running.
9. Only heparin or citrate may be used as anticoagulants. Do not use EDTA diluted blood.
10. The test results are valid only when read 15 minutes after the sample has been applied.
11. The results of the rapid test should only be evaluated in the context of other laboratory values and the patient’s clinical status.
12. All patient samples should be considered to be potentially infectious.
13. Always wear disposable gloves.

Storage and stability

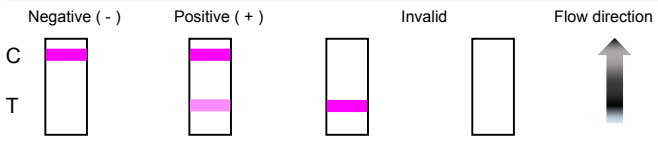
The QuickSens® CRP test is stable until the expiry date printed on the package when stored between **+2°C and +8°C / 36°F and 46°F**. The test should be used on the same day after it has been removed from the sealed bag.

Performing the test

Step 1 Open the sealed bag, remove the test and place it on a horizontal surface.
Step 2 The test must be at room temperature prior use.
Step 3 Label the test with the patient’s identification.
Step 4 Open a vial with dilution buffer and add **10 µl** of whole blood, plasma or serum using a pipette. Close the vial and shake **gently**.
Step 5 Apply **120 µl** of the diluted sample in the sample reservoir (“S”).
Step 6 Read the test result for whole blood or plasma or serum **after 15 minutes**.

Interpretation of the test results

The red/purple control line (“C”) indicates whether the test has worked properly. If the control line (“C”) does not appear, the test has to be repeated with a new test. In this case please carefully read the instruction for use again and repeat the testing.



Note! If a result cannot be clearly interpreted, a rerun with a new test is necessary.

For a semi-quantitative determination of the CRP level, please use the enclosed lot-specific reference card (optional). Using this reference card the CRP concentration can easily be allocated to a diagnostically relevant range. The following results may occur in a practical application:

Negative (-)

< 5.0 mg/l: The control line (“C”) is visible. There is, however, **no** test line. This means that an inflammation can be ruled out with a high degree of certainty.

Positive (+)

≥ 5.0 mg/l: A red/purple line appears in the upper section of the panel (control line “C”) indicating that the test worked properly and another red/purple line in the lower section (test line “T”) indicates a positive result. The stronger and wider the line, the higher the CRP value. To determine the exact concentration, the lot-specific reference card (optional) or the QuickSens® Ω100 reader can be used.

The determined CRP concentration provides an indication of the severity of the disease. Typical examples are:

- **10.0 ... 50.0 mg/l:** Typical of slight or local bacterial infections, chronic infections (TBC, syphilis, brucellosis), rheumatic arthritis, psoriatic arthritis, collagenosis, Collitis ulcerosa and intrauterine infections. Please note that the CRP level may be slightly elevated for smokers, patients performing endurance sports and during pregnancy.
- **> 50.0 mg/l:** Typical of severe bacterial infections (sepsis), bacterial meningitis, pneumonia, active rheumatic arthritis, systemic vasculitis, active Crohn's disease, thrombosis, acute pancreatitis and for metastasizing tumors.

Please note that the CRP level may rise in the case of slight inflammatory processes also. Compared to the marker procalcitonin, CRP responds more sensitively and can therefore be used to monitor the progress of a disease or the course of a tissue rejection after organ transplants.

Viral infections usually lead to non or only slightly elevated CRP levels.

Invalid

No control line (“C”) appears.

Functional control

QuickSens® CRP test contains an internal function control (control line “C”). This indicates that a sufficient sample volume has been applied and the chromatography worked properly.
Good Laboratory Practices recommend the use of positive and negative controls. The package does not contain control standards, but they are optionally available at 8sens.biognostic GmbH (Article no.: LF 01002-01).

Sample material

The test works with both capillary as well as venous whole blood. It may be used with or without added anticoagulants heparin or citrate. EDTA is not permitted as an additive. The test also works with plasma or serum.
Sample volume: 120 µl
Stability of CRP in whole blood, plasma and serum samples:
- At ambient temperature: 15 days
- At +4 bis +8°C: 2 months
- At –20°C: 3 years (plasma and serum only)

Blood samples must not be frozen. Do not repeatedly freeze and thaw the plasma or serum samples.

Disposal

All clinical samples must be disposed of in accordance to the appropriate regulations, respectively after being autoclaved, all samples and used tests may be disposed of in the domestic waste.

Key to symbols

	Consult instruction for use		Temperature limits (storage)
	For single use only	LOT	Batch no.
	Sufficient for n tests		Expiry date YYYY-MM (EXP)
REF	Reference no.		Manufacturer
IVD	In-vitro-diagnostic		

References

- Weis N, Almdal T. C-reactive protein - can it be used as a marker of infection in patients with exacerbation of chronic obstructive pulmonary disease? Eur J Intern Med (2006) 17:88-91.
- Póvoa P, Coelho L, Almeida E, Fernandes A, Mealha R, Moreira P, Sabino H. Early identification of intensive care unit-acquired infections with daily monitoring of C-reactive protein: a prospective observational study. Critical Care (2006) 10(2) R63:1-8.
- Flanders SA, Stein J, Shochat G, Sellers K, Holland M, Maselli J, Drew WL, Reingold AL, Gonzales R. Performance of a bedside C-reactive protein test in the diagnosis of community-acquired pneumonia in adults with acute cough. Am J Med (2004) 116(8):529-535.
- Dahler-Eriksen BS, Lauritzen T, Lassen JF, Lund ED, Brandslund I. Near-Patient test for C-reactive protein in general practice: assessment of clinical, organizational and economic outcomes. Clin Chem (1999) 45(4):478-485.

CE **IN-VITRO-DIAGNOSTIC TEST – FOR PROFESSIONAL USE ONLY**

Rev. 11 EN

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