Instruction for use

QuickSens® hs-CRP

Rapid test for the highly sensitive determination of C-reactive protein (CRP) in whole blood, plasma or serum
Reference no.: LF01001

Application

QuickSens® hs-CRP is an immuno-chromatographic test for the highly sensitive 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® hs-CRP is a reliable test to evaluate the cardiovascular risk because the CRP level is increased for low-level, chronic systemic inflammations. Patients with a CRP concentration in the range of 2.1-7.9 mg/l are known to have a 2.5 times higher risk to suffer a cardiovascular event than those whose CRP value is low (about 1.0 mg/l).

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.

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 will be formed as follows: first, the sample fluid releases the gold-labelled anti-CRP-antibody from its matrix within the test strip. CRP 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® hs-CRP tests
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. Avoid touching the test area and do not apply any liquid other than into the sample reservoir ("S").
7. Do not press on the cassette while the test is running.
8. Only heparin or citrate may be used as anticoagulants. Do not use EDTA diluted blood.
9. The test results are valid only when read 15 minutes after the sample has been applied.
10. The results of the rapid test should only be evaluated in the context of other laboratory values and the patient's clinical status.
11. All patient samples should be considered to be potentially infectious.
12. Always wear disposable gloves.

Storage and stability

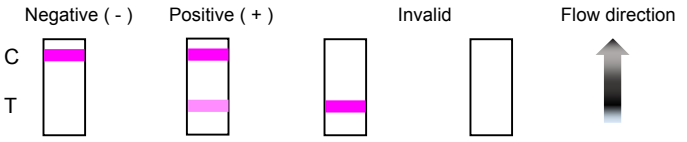
The QuickSens® CRP test is stable until the expiry date printed on the package when stored between **+2°C and +8°C / 36°F and 46°F**. The test should be used on the same day after it has been removed from the sealed bag.

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 Apply **120 µl** of the diluted sample in the sample reservoir ("S").
Step 5 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 (-)

< 0.5 mg/l: The control line ("C") is visible. There is, however, **no** test line.

Positive (+)

≥ 0.5 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.
Values > 3.0 mg/l are indicative of a considerably increased cardiac risk. The higher the measured CRP concentration, the higher the risk to suffer from a cardiovascular event in the future.

Caution! For technical reasons CRP concentrations between 10.0 mg/l and 25.0 mg/l will lead to identical results. Concentrations > 25.0 mg/l are not quantifiable with QuickSens® hs-CRP. In this case the test will then show concentrations lower than real. Values above 25.0 mg/l can be expected in the presence of the following diseases: bacterial infections, different inflammatory diseases, lesions (also postoperative ones), burns, numerous malignant tumors, rheumatic diseases, sarkoidosis, chronic infections, collagenosis, Crohn's disease, thrombosis, pancreatitis and others. In addition, during pregnancy and in smokers elevated CRP values are typical.
In case of doubt, it is recommended to complement the QuickSens® hs-CRP with a normal CRP test (e.g. QuickSens® CRP) which can measure concentrations up to 100.0 mg/l. Alternatively, the sample may be diluted 1:10 using physiological saline solution (0.9 % NaCl). The testing procedure should then be repeated with a new QuickSens® hs-CRP test.
If there is still a positive signal, this indicates a very high CRP level and QuickSens® hs-CRP can not be used for evaluating the heart risk for this patient.

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 01001-01).

Features and limitations

Sensitivity: 84.4 %
Specificity: 89.1 %

Analytic accuracy

The inter-batch test showed that samples were properly identified in > 99 % of the cases.
The intra-batch test showed that samples were properly identified in > 99 % of the cases.

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	2 °C 8 °C	Temperature limits (storage)
	For single use only	LOT	Batch no.
Σ n	Sufficient for n tests	YYYY-MM	Expiry date YYYY-MM (EXP)
REF	Reference no.		Manufacturer
IVD	In-vitro-diagnostic		

References

- Michael B. Clearfield, DO. C-reactive protein: a new risk assessment tool for cardiovascular disease. JAOA (2005) 105 (9):409-416.
- Gotto AM Jr. Role of C-reactive protein in coronary risk reduction: focus on primary prevention. Am J Cardiol (2007) 99 (5): 718-725.
- Mora S, Rifai N, Buring JE, Ridker PM. Additive value of immunoassay-measured fibrinogen and high-sensitivity C-reactive protein levels for predicting incident cardiovascular events. Circulation (2006) 114 (5): 381-387.

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

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