Instruction for use

QuickSens® cTnI

Rapid test for the determination of cardiac Troponin I (cTnI) in whole blood, plasma or serum
Reference no.: LF01003

Intended use

QuickSens® cTnI is an immuno-chromatographic test for the determination of cTnI in whole blood, plasma or serum. With the QuickSens® Ω100 optoelectronic reader (optional) it is possible to perform an exact quantification. QuickSens® cTnI is suitable for the detection or exclusion of an acute myocardial infarction (AMI) and is used in suspected cases.

Principle of the test

The test contains different specific monoclonal antibodies for cardiac Troponin I, some of which are gold-labelled and the others are biotinylated. The sample releases the gold-labelled and the biotinylated anti-cTnI-antibodies out of their matrices.
If the sample to be examined contains cTnI, the antibodies form a sandwich complex (anti-cTnI-antibody (gold-labelled) ↔ cTnI ↔ anti-cTnI-antibody (biotinylated)). This complex flows over the test strip.
Streptavidin is located at the "T"- position and binds the complex via biotin. Depending on the concentration of cTnI 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 cTnI.
If the sample does not contain cTnI, no complex can be formed and therefore no test line will appear.
Excess gold-labelled antibodies bind non-specific to the control line ("C"), indicating that the test worked properly.

Contents of package

25 disposable QuickSens® cTnI tests
1 instruction for use

Additional material required

- Blood sample vessel with heparin, citrate or EDTA 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. Deviations from the test instructions described here can lead to incorrect results.
3. The test must reach room temperature prior to use.
4. Do not use the test beyond the expiry date.
5. Use the exact sample volume specified in the section "Specimen".
6. Avoid touching the test area and do not apply any liquid.
7. Do not press on the cassette while the test is running.
8. Heparin, citrate or EDTA may be used as anticoagulants.
9. The test result is valid only when read 15 minutes after the sample has been applied.
10. The result of the rapid test should only be evaluated in context with 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

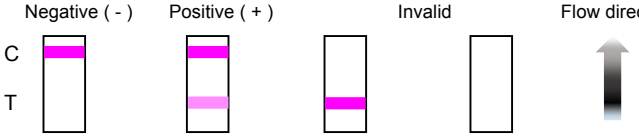
The QuickSens® cTnI test is stable until the expiry date printed on the package when stored between **+2°C and +8°C / 36°F and 46°F**. The test should be used on the same day after it has been removed from the sealed bag.

Procedure

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** whole blood, plasma or serum in the sample reservoir ("S").
Step 5 Read the test result for whole blood or plasma or serum **after 15 minutes**.

Interpretation of 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.

Negative (-)

< 1.0 ng/ml: The control line ("C") is visible. There is, however, **no** test line.

Positive (+)

≥ 1.0 ng/ml: 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 cTnI value. To determine the exact concentration the QuickSens® Ω100 reader can be used.

Invalid

No control line ("C") appears.

Functional control

The QuickSens® cTnI 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 Practice recommends the use of positive and negative controls. The package does not contain control standards, but they are optionally available at 8sens.biognostic GmbH (Reference no.: LF01003-01).

Features and limitations

Sensitivity: 97.5 %
Specificity: 96.6 %

A **negative test result** does not exclude the possibility of a myocardial infarction having occurred.

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 and venous whole blood. It may be used with or without added anticoagulants (heparin, citrate or EDTA). The test also works with plasma or serum.
Sample volume: 120 µl
Sample shelf life: Blood samples should be used within 8 hours after collection and must not be frozen. Do not repeatedly freeze and thaw 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.
n	Sufficient for n tests		Expiry date YYYY-MM (EXP)
REF	Reference no.		Manufacturer
IVD	In-vitro-diagnostic		

References

- Stacy C. Smith, MD; Jack H. Ladenson, PhD; Jay W. Mason, MD; Allan S. Jaffe, MD. Elevations of Cardiac Troponin I associated with myocarditis. Circulation 1997; 95:163- 168
- Conor J. McCann, Ben M. Glover, Ian B.A. Menown, Michael J. Moore, Jane McEneny, Colum G. Owens, Bernie Smith, Peter C. Sharpe, Ian S. Young, and Jennifer A. Adgey. Novel biomarkers in early diagnosis of acute myocardial infarction compared with cardiac Troponin T. European Heart Journal (2008) 29, 2843-2850
- Jørgen Gravning and John Kjekshus. The perfect biomarker in acute coronary syndrome: a challenge for diagnosis, prognosis, and treatment. European Heart Journal (2008) 29, 2827-2828

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Rev. 09 EN

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