Instruction for use

QuickSens® h-FABP

Quantitative rapid test for the determination of heart-type Fatty Acid-Binding Protein (h-FABP) in whole blood, plasma or serum
Reference no.: LF01004

Application

QuickSens® h-FABP is an immuno-chromatographic test for the determination of h-FABP in whole blood, plasma or serum. QuickSens® h-FABP 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 two different specific monoclonal antibodies for h-FABP, one of which is gold-labelled and the other one biotinylated. The sample releases the gold-labelled and the biotinylated anti-h-FABP antibodies out of their matrices.
If the sample to be examined contains h-FABP, the antibodies form a sandwich complex with the analyte (anti-h-FABP-antibody (gold-labelled) ↔ h-FABP ↔ anti-h-FABP-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 h-FABP 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 h-FABP.
If the sample does not contain h-FABP, no complex can be formed and therefore no test line will appear.
The excess gold-labelled antibodies bind unspecific at the control line ("C") and indicate that the test has worked properly.

Contents of package

25 disposable QuickSens® h-FABP tests
1 instruction for use

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
- Optoelectronic reader QuickSens® Ω100

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 the 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

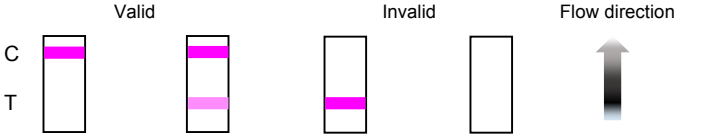
The QuickSens® h-FABP test is stable until the expiry date printed on the package when stored between **+2°C and +8°C / 36°F and 46°F**. The test should be used on the same day after it has been removed from the sealed bag.

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** whole blood, plasma or serum in the sample reservoir ("S").
Step 5 Read out the test result **after 15 minutes** by using the reader QuickSens® Ω100.

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.

Valid test

The control line ("C") is visible. The concentration is quantified by the reader QuickSens® Ω100 (test line).

Invalid test

No control line ("C") appears.

Functional control

The QuickSens® h-FABP 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 (Article no.: LF01004-01).

Features and limitations

Measuring range: 0.6 - 75 ng/ml
Cut off: 5.4 ng/ml

Sensitivity: 95.3 %
Specificity: 96.2 %

A **negative test result** (< 5.4 ng/ml) does exclude the possibility of a myocardial infarction having occurred almost certainly.

A **positive test result** (≥ 5.4 ng/ml) indicates an acute myocardial infarction.

The h-FABP concentration may be elevated in patients with renal failure or angina pectoris. Small amounts of h-FABP are also present in skeletal muscle. Patients who got exercise prior to the test or professional athletes may have elevated h-FABP concentrations, which may lead to a false positive result.
To date there are no known drugs which, when applied in therapeutic dosages, affect the test.

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
Sample shelf life: Blood samples should be tested within 8 hours of collection and must not be frozen. Do not repeatedly freeze and thaw plasma or serum sample.

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.
Σ n	Sufficient for n tests	YYYY-MM	Expiry date YYYY-MM (EXP)
REF	Reference no.		Manufacturer
IVD	In-vitro-diagnostic		

References

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- Claudia Dellas, MD, Miriam Puls, MD, Mareike Lankeit, MD, Katrin Schäfer, MD, Mayumi Cuny, MD, Maik Berner, MD, Gerd Hasenfuss, MD and Stavros Konstantinides, MD. Elevated Heart-Type Fatty Acid-Binding Protein Levels on Admission Predict an Adverse Outcome in Normotensive Patients With Acute Pulmonary Embolism, JACC, Vol. 55, No. 19, 2010
- Karthik Viswanathan, MD, Niamh Kilcullen, MD, Christine Morrell, Sue J. Thistlethwaite, Mohan U. Sivananthan, MD, Tajek B. Hassan, MD, Julian H. Barth, MD and Alistair S. Hall, MD, PhD. Heart-Type Fatty Acid-Binding Protein Predicts Long-Term Mortality and Re-Infarction in Consecutive Patients With Suspected Acute Coronary Syndrome Who Are Troponin-Negative. JACC, Vol. 55, No. 23, 2010

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

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