1. **Intended Use**
The NADAL® h-FABP Test is an immunological Rapid Test for the qualitative detection of human h-FABP (Myocardial infarction diagnosis) in Whole blood, Serum or Plasma.

2. **Introduction and/or Clinical Significances**
Heart disease, including Heart Attack is the second leading cause of death in the world. Normal function of the heart muscle requires a high level of oxygen supply; even a brief interruption in this supply can lead to death of the tissue. Studies show that every year 1.1 Million Americans suffer from a heart attack. 50% of which are fatal. Nearly 20% of patients die before they reach hospital. Therefore rapid diagnosis and treatment of a heart attack is the most important step in saving a patient. h-FABP (heart type Fatty Acid Binding Protein) is a protein in heart muscle cells, whose primary function is to transport free fatty acids. Through a heart attack related interruption of blood supply, h-FABP can be detected in peripheral blood within 20 minutes. This makes h-FABP a highly specific biochemical marker for early detection of a heart attack.

3. **Principle of the Test**
The NADAL® h-FABP Test is an immunological Rapid Test for the detection of h-FABP in Whole blood, Serum and Plasma. In the test line area a line will appear. In the assay, the sample material will first react with the Anti-h-FABP antibodies, forming a complex. This complex moves by capillary effect through the test area of the membrane- If h-FABP is found in the sample, the complex binds to the T-Zone and a line will be visible. This should be interpreted as a positive result. If the sample contains no h-FABP, no line will appear in the T-Zone, and this should be interpreted as a negative result. A line in the control zone confirmed the correct amount of sample volume.

4. **Reagents and Materials Supplied**
- 10 NADAL®-h-FABP Test cassettes including single use pipettes.
- 1 bottle of Buffer solution (only for use with Whole blood)
- 1 User Manual

5. **Additional Required Materials**
- Sample collector
- Stop watch
- Centrifuge
- Lancet (only for whole blood from the finger-tip)
- Heparinised capillary (only for whole blood from the finger-tip)

6. **Storage & Stability**
All Reagents included within the NADAL®-h-FABP Test Cassette can be stored at room temperature or refrigerated at (4°C-30°C).

7. **Warnings and Precautions**
- Only for in vitro use.
- Only for professional use.
- Only for single use.
- The test cassette should remain in the foil packaging until use.
- Single use gloves should be used for test procedure.
- No reagents from different lots should be used.
- All samples should be handled if potentially infectious.
- False positive results can occur in case of renal failure, skeletal muscle injury, Angina Pectoris or long lasting sporting stress, e.g. with professional athletes.
- This test is for test he existence of h-FABP in the sample given, and should not be used as the only evidence in the diagnosis of a heart attack.
- If the test result is negative and there are clinical symptoms, further diagnostic tests should be carried out.
- Do not use after expiration date.
- No smoking, eating or drinking in the presence of the test procedure.
- Do not use the test, if the foil packaging is damaged.
- Please be aware of necessary sample volume.
- Do not put sample in the Reaction field (results field).
- Please pay attention to the evaluation time (10 Minutes).
- Tests should be stored and transported at the correct temperature.

8. **Specimen Collection and Preparation**
The test can be performed with whole blood, serum and plasma sample materials. Hemolysis in Serum und Plasma should be avoided in the performance of the test.

**Sample Taking**

**Whole Blood**
The test procedure should be performed immediately after sampling. Alternatively the sample can be stored at 2 – 8°C with anticoagulant (EDTA, Heparin or Citrate should be used) for 2 days until the testing procedure.

**Serum**
The sample material should be collected in a sample tube without anticoagulant, wait 30 Minutes for coagulation, and then centrifuge. The Supernatent after centrifugation is the Serum to be used.

Plasma
The sample material should be collected in a sample tube with anticoagulant (EDTA, Heparin or Citrate) and then centrifuge. The Supernatent after centrifugation is the Plasma to be used.

**Sample Storage**
- Do not use cloudy, haemolysed samples.
- If the sample material cannot be used the sample day, store the Serum or Plasma in a refrigerator or freezer.
- Freezing and thawing of Serum and Plasma should not be repeated quickly.
- Do not freeze whole blood.
- Bring the sample material to room temperature before performing the test.
- Cloudy sample material should be centrifuged.

9. **Procedure of the Test**

**General Notes**
- All samples and reagents of the NADAL®-h-FABP Tests should be brought to room temperature (15-30°C) before the test procedure.

**Test Procedure with the Casette Test**

**Whole Blood**
1) Take the NADAL®-h-FABP Test cassette and the included single use pipette out of the foil packaging and lay the test cassette on a flat surface. Take the pipette between the thumb and innex finger and squeeze the pipette ballon together. Enter the pipette in the sample tube and then by slow pressure on the end of the pipette draw up some of the sample.

2) Place one (1) drop (ca. 30 µl) of the sample in the sample well of the cassette test by squeezing the end of the pipette.

3) Place one (1) drop (ca. 40 µl) of the buffer solution in a sample well of the cassette test.

4) Depending on the h-FABP concentration in the sample, the test can indicate a result after 5 Minutes. Results should be read after 10-15 Minutes. After 15 minutes results should no longer be read.

**Serum und Plasma**
1) Take the NADAL®-h-FABP Test cassette and the included single use pipette out of the foil packaging and lay the test cassette on a flat surface. Take the pipette between the thumb and innex finger and squeeze the pipette ballon together. Enter the pipette in the sample tube and then by slow pressure on the end of the pipette draw up some of the sample.

2) Place two (2) drops (ca. 60 µl) of the sample in the sample well of the cassette test by squeezing the end of the pipette.

3) Place no buffer solution in the sample well of the cassette test.

4) Depending on the h-FABP concentration in the sample, the test can indicate a result after 5 Minutes. Results should be read after 10-15 Minutes. After 15 minutes results should no longer be read.

10. **Interpretation of the Results**

**Positive**
Along with a coloured line in the Control region (C) a coloured line will should in the Test region (T). The colour intensity of the test line can vary depending on the concentration present. This result indicates that h-FABP is present in the sample.

**Negative**
A line appears in the control region (C); No line is visible in the Test region (T). h-FABP is not present.

**Invalid**
No line in the control region indicates an error in the test procedure. The investigation should be repeated with a new test.
11. Quality Control

The NADAL®-h-FABP Test includes an internal control (C-Linie), which indicates whether a sufficient amount of sample material was applied to the test and that the Lateral chromatography has been performed correctly. Control standards are not supplied with the NADAL®-h-FABP Test. The implementation of positive and negative controls is recommended as good laboratory practice (GLP).

12. Limitations

- The detection limit of NADAL®-h-FABP lies at 6.5 ng/l.
- The NADAL®-h-FABP Test is intended only for in vitro Diagnostic use for the detection of h-FABP in Whole blood, Serum or Plasma.
- The NADAL®-h-FABP Test only confirms the presence of h-FABP in the sample and should not be used as sole criteria for diagnosis.
- As with all diagnostic tests the results together with other clinical information should be evaluated by a physician.

13. Performance Characteristics

Cross-Reaction Study

Further cross-reaction studies were performed with NADAL®-h-FABP Test cassette. For samples of 110 mg/mL human Albumin, 6 mg/mL Bilirubin, 10 mg/mL Haemoglobin, 5 mg/mL Cholesterol and 15 mg/mL Triglycerides no reaction was observed.

The following substances were also tested with NADAL®-h-FABP Test cassettes from nov von mindent, there were no cross reactions at a concentration of 50 µg/mL for the following substances.

<table>
<thead>
<tr>
<th>Substance</th>
<th>Concentration</th>
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<tbody>
<tr>
<td>Acetaminophen</td>
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<tr>
<td>Acetylsalicylic acid</td>
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<tr>
<td>Anisodamine</td>
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<td>Ascorbic Acid</td>
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<td>Atenolol</td>
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<td>Atorvastatin Calcium</td>
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<td>Chloramphenicol</td>
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<td>Furosemide</td>
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14. References


