SensAheart – One Step cardiac FABP Test

IVD

For the qualitative determination of cardiac troponin I in human whole blood/serum/plasma (20 tests).

Catalog # R-6503 ***For miniature size samples***

INTENDED USE

The *Novamed* One Step cardiac FABP Test Device is intended for the qualitative determination of cardiac FABP in human whole blood. Measurement of FABP values is useful in the evaluation of acute myocardial infarction (AMI).

ASSAY SUMMARY

The human cardiac FABP (H-FABP or FABP3) is a 132 amino acid small molecular weight (15kDa) protein[1]. FABP3 is one of the most abundant proteins in cardiomyocytes and is mainly involved in fatty acid transport[2]. The concentration of fatty acids in plasma and in myocardial tissue rise during myocardial ischemia acting to protect myocytes against fatty acid oxidation[3-7]. Upon acute myocardial infarction (AMI) the blood and urine levels of FABP3 rise rapidly[8-10] (within 1-3 hours) reaching their peak values at 6 hours, and return to baseline concentration within 24 hours. Characteristics of FABP3 appear to be similar to those of myoglobin[11-14], however, FABP3 concentrations are 2–10-fold higher in the heart than in the skeletal muscle[15, 16]. In contrast, myoglobin concentrations are 2-fold lower in cardiac cells than skeletal cells. Thus, the apparent greater cardiospecificity of FABP3, along with certain aspects of its biology account for its greater value in diagnostics of AMI[16-20]

TEST PRINCIPLE

The *Novamed* One Step cardiac FABP Test Device is a lateral flow-based immunoassay designed for the detection of FABP3 in miniature-sized human whole blood, plasma and serum samples. To perform the test, sample is loaded onto the assay sample input surface through the sample port opening. The vast majority of blood cells, if present in the sample, are immediately filtered out owing to the unique architecture of the test, allowing only the plasma to flow down the assay membrane. FABP3 in the specimen is bound by, and forms a complex with colloidal gold-conjugated mouse-anti-FABP3 monoclonal antibodies. This complex migrates through the membrane towards the assay test line containing additional murine monoclonal antibodies where a color band of variable intensity should be observed when the FABP3 concentration is greater than or equal to 10ng/ml, the assay sensitivity limit. No line will appear in the test line area if specimen FABP3 concentration is below this limit. The specimen-gold conjugate mixture then migrates further down the membrane through the assay control line to produce a color band. The assay is deemed invalid if the control line is not visible, and retesting should be performed.

KIT COMPONENTS

Each kit contains everything needed to perform 20 tests.

- 20 individually wrapped test devices.
- 1 dropper bottle with buffer
- 1 package insert.

STORAGE AND STABILITY

The test device should be stored at ambient temperature 15-25°C in its sealed pouch and under dry conditions. Expiration date for each assay lot is indicated on the pouch. **Do not use if foil pouch seal is not intact!**

WARNINGS AND PRECAUTIONS

1. For *in-vitro* diagnostic use only.
2. Always wear gloves when performing this procedure and treat all specimens and used devices as potentially infectious.
3. The *Novamed* One Step cardiac FABP Test Device should remain in foil pouch until ready for use. The pouch containing the test card must be completely sealed.
4. Do not use the *Novamed* One Step cardiac FABP Test Device beyond the expiration date printed on foil pouch.

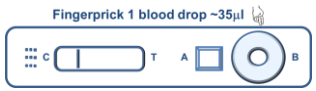
TEST LIMITATIONS

The *Novamed* One Step cardiac FABP Test is a qualitative assay device capable of detecting elevations of FABP3 levels above 10ng/ml. A positive test result from a patient suspected of AMI requires further confirmation. To diagnose cardiac emergencies, SensAheart should not be used as a sole diagnostic means, but in conjunction with other data, such as clinical signs, and EKG. Caution should be exercised when interpreting results obtained from samples expressing elevated level of substances known to interfere with lateral flow format tests, such as rheumatoid factor or antinuclear antibody, produced in certain diseases. These substances are generally known to impose false positive and false negative results.

DIRECTIONS FOR USE

1. Bring the pouch to room temperature. Remove the test device from the sealed pouch and use it as soon as possible. For best results use immediately after opening the pouch
2. Place the test device on a clean and level surface.

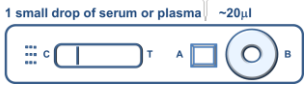
a. Whole blood Allow 1 hanging drop of fingerprick whole blood specimen (approximately 35-40 µL) to fall into the center of well **B** on the test device. After the sample is fully absorbed, wait 15-20 seconds and add 4 drops of buffer **to the same well (B)**. See illustration below.



Add 4 drops of buffer
Read results at 15-20 minutes.
Do not interpret after 20 minutes.

b. Serum/Plasma Apply 20 µL of serum/plasma to well **A**. Wait ~10 seconds and then add 6 drops of buffer to well **B**.

3. Wait for the colored line(s) to appear.



Add 6 drops of buffer
Read results at 15-20 minutes.
Do not interpret after 20 minutes.

QUALITY CONTROL

An internal procedural control is included in the test. A colored line in the control line region **(C)** is an internal procedural control. It confirms sufficient specimen volume, adequate membrane wicking and correct procedural technique.

INTERPRETATION OF RESULTS

(Please refer to the illustration below)

POSITIVE:* Two distinct colored lines appear. One vivid colored line is visible in the control line region **(C)**, and another apparent colored line should be detected in the test line region **(T)**.

***IMPORTANT NOTE:** The intensity of color in the test line region **(T)** is subject to variability reflecting the concentration of FABP3 present in the specimen. Therefore, any shade of color in the test line region (Test) should be considered positive.

Positive test

NEGATIVE: One colored line appears in the control line region (C). No line is visible in the test line region **(T)**.

Negative test

INVALID: Control line (C) fails to appear. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test with a new test device. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

Invalid test

CROSS-REACTIVITY

Sera containing known amounts of FABP4 (≤10000 ng/ml), and cardiac Troponin I (≤5000 ng/ml) have been tested with the device. No cross-reactivity was observed.

REFERENCES

1. Zimmerman AW, Veerkamp JH. New insights into the structure and function of fatty acid-binding proteins. Cell Mol Life Sci 2002;59:1096-116.
2. Colli A, Josa M, Pomar JL, Mestres CA, Gherli T. Heart fatty acid binding protein in the diagnosis of myocardial infarction: where do we stand today? Cardiology 2007;108:4-10.
3. Fournier NC, Richard MA. Role of fatty acid-binding protein in cardiac fatty acid oxidation. Mol Cell Biochem 1990;98:149-59.
4. Liedtke AJ, Nellis S, Neely JR. Effects of excess free fatty acids on mechanical and metabolic function in normal and ischemic myocardium in swine. Circ Res 1978;43:652-61.
5. Opie LH, Tansey M, Kennelly BM. Proposed metabolic vicious circle in patients with large myocardial infarcts and high plasma-free-fatty-acid concentrations. Lancet 1977;2:890-2.
6. Philipson KD, Ward R. Effects of fatty acids on Na+-Ca2+ exchange and Ca2+ permeability of cardiac sarcolemmal vesicles. J Biol Chem 1985;260:9666-71.
7. Knowlton AA, Apstein CS, Saouf R, Brecher P. Leakage of heart fatty acid binding protein with ischemia and reperfusion in the rat. J Mol Cell Cardiol 1989;21:577-83.
8. Glatz JF, Paulussen RJ, Veerkamp JH. Fatty acid binding proteins from heart. Chem Phys Lipids 1985;38:115-29.
9. Schaap FG, van der Vusse GJ, Glatz JF. Fatty acid-binding proteins in the heart. Mol Cell Biochem 1998;180:43-51.
10. Panteghini M. Standardization activities of markers of cardiac damage: the need of a comprehensive approach. Eur Heart J 1998;19 Suppl N:N8-11.
11. de Winter RJ, Lijmer JG, Koster RW, Hoek FJ, Sanders GT. Diagnostic accuracy of myoglobin concentration for the early diagnosis of acute myocardial infarction. Ann Emerg Med 2000;35:113-20.
12. Stork TV, Wu AH, Muller-Bardorff M, Gareis R, Muller R, Hombach V, Katus H, Mockel M. Diagnostic and prognostic role of myoglobin in patients with suspected acute coronary syndrome. North-Wurttemberg Infarction Study (NOWIS) Group. Am J Cardiol 2000;86:1371-4, A5.
13. Panteghini M, Apple FS, Christenson RH, Dati F, Mair J, Wu AH. Proposals from IFCC Committee on Standardization of Markers of Cardiac Damage (C-SMCD): recommendations on use of biochemical markers of cardiac damage in acute coronary syndromes. Scand J Clin Lab Invest Suppl 1999;230:103-12.
14. Wu AH, Apple FS, Gibler WB, Jesse RL, Warshaw MM, Valdes R, Jr. National Academy of Clinical Biochemistry Standards of Laboratory Practice: recommendations for the use of cardiac markers in coronary artery diseases. Clin Chem 1999;45:1104-21.
15. Van Nieuwenhoven FA, Kleine AH, Wodzig WH, Hermens WT, Kragten HA, Maessen JG, Punt CD, Van Dieijen MP, Van der Vusse GJ, Glatz JF. Discrimination between myocardial and skeletal muscle injury by assessment of the plasma ratio of myoglobin over fatty acid-binding protein. Circulation 1995;92:2848-54.
16. Kragten JA, van Nieuwenhoven FA, van Dieijen-Visser MP, Theunissen PH, Hermens WT, Glatz JF. Distribution of myoglobin and fatty acid-binding protein in human cardiac autopsies. Clin Chem 1996;42:337-8.
17. de Groot MJ, Muijtjens AM, Simoons ML, Hermens WT, Glatz JF. Assessment of coronary reperfusion in patients with myocardial infarction using fatty acid binding protein concentrations in plasma. Heart 2001;85:278-85.
18. Haastrup B, Gill S, Kristensen SR, Jorgensen PJ, Glatz JF, Haghfelt T, Horder M. Biochemical markers of ischaemia for the early identification of acute myocardial infarction without St segment elevation. Cardiology 2000;94:254-61.
19. Ishii J, Wang JH, Naruse H, Taga S, Kinoshita M, Kurokawa H, Iwase M, Kondo T, Nomura M, Nagamura Y, Watanabe Y, Hishida H, Tanaka T, Kawamura K. Serum concentrations of myoglobin vs human heart-type cytoplasmic fatty acid-binding protein in early detection of acute myocardial infarction. Clin Chem 1997;43:1372-8.
20. Nakata T, Hashimoto A, Hase M, Tsuchihashi K, Shimamoto K. Human heart-type fatty acid-binding protein as an early diagnostic and prognostic marker in acute coronary syndrome. Cardiology 2003;99:96-104.

Manufactured by Novamed ltd. 28 Pierre Koenig st. POB 53231 Jerusalem 91531 ISRAEL
TEL. 972-2-6781861 FAX. 972-2-6781852 e-mail: info@novamed.co.il

CE EC REP MedNet GmbH * Borkstrasse 10 * 48163 Muenster * Germany
Phone +49 251 32266-60 * Fax +49 251 32266-22