DS Pharma Biomedical

LIBLIA® H-FABP

H-FABP

LIBLIA® H-FABP is a reagent for quantification of H-FABP in serum or plasma based on latex-agglutination immunoassay method.

Heart-type fatty acid-binding protein (H-FABP) is a low-molecular-weight (15KDa) cytoplasmic protein involved in the intracellular uptake and buffering of free fatty acids in the myocardium[1]. When the myocardium is injured, H-FABP is easily released into the circulation and it can be detectable even if in super-acute phase within 2-4hrs after the onset of symptoms. Therefore, H-FABP is thought to be an excellent biomarker for acute myocardium damage that is Acute Coronary Syndrome (ACS), heart failure, etc.

LIBLIA® H-FABP is quick and convenient reagent based on latex-agglutination method, it's one of the most useful emergency laboratory test for detection of myocardial damage.

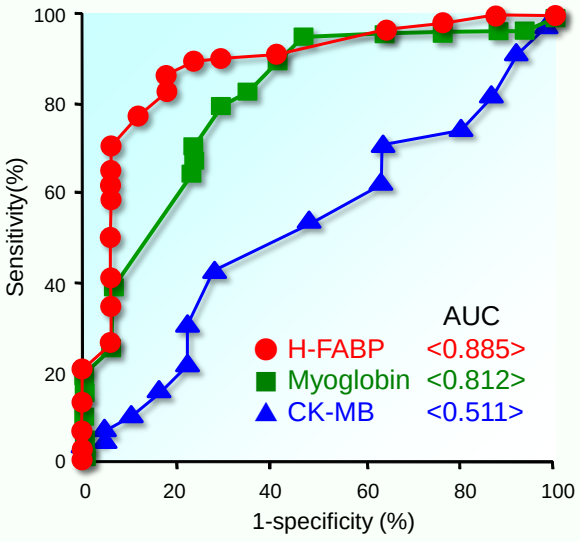

Figure-1. ROC Curves of H-FABP, Myoglobin and CK-MB within 3hr after the onset of symptoms [3].

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DS Pharma Biomedical Co., Ltd.
33-94 Enoki, Suita
Osaka 564-0053, JAPAN
http://www.dsp-bio.com
TEL +81-6-6337-5941
FAX +81-6-6337-6020

LIBLIA® H-FABP

■Intended Use

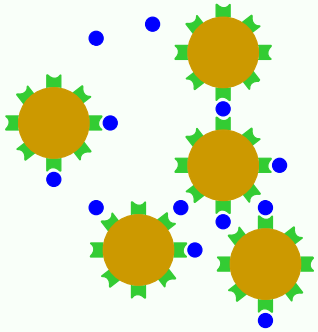
For the quantitative measurement of H-FABP in serum or plasma.

■Summary

H-FABP is sensitive and early marker for myocardial injury. Especially, H-FABP is famous as new marker of the Acute Coronary Syndrome (ACS) diagnosis, the potential of it as one of the most sensitive marker in super-acute phase within 2-4hr from onset[2-6]. H-FABP can be detectable in a sample from the patient who has small myocardial injury, therefore it is useful marker of acute heart failure patient's condition grasp, too[7-9]. Additionally, it has been reported that prognostic utility of H-FABP in patients with ACS in spite of with/without High Sensitive Troponins[10-12].

■Principle

The LIBLIA H-FABP is an latex-agglutination turbidimetric immunoassay. Sample is added to a buffer solution and mixed with a suspension of mouse anti-human H-FABP monoclonal antibody that is bound to latex. H-FABP binds to the latex-bound antibody and agglutinates. The light scattering caused by the increase in particle size is used as a measure of H-FABP concentration. The amount of light scattering is proportional to the concentration of H-FABP in the sample.



■Reagents

Composition

・R1-Reagent: Liquid, ready to use.　・R2-Reagent: Liquid, ready to use.

Storage and Expiry period

・Storage: Store in a cool place (2-10°C), protected from light. Avoid freezing.　・Expiry period: 1 years

■Specimen Collection and Preparation

Serum, EDTA-plasma, and sodium or lithium heparinized-plasma are the recommended collection media. If not analyzed within 24hrs, they may be preserved at –20°C or below.

■Assay Procedure

Figure-1 is a general example of the LIBLIA H-FABP assay procedure for an automated analyzer. All analyzer applications should be validated.

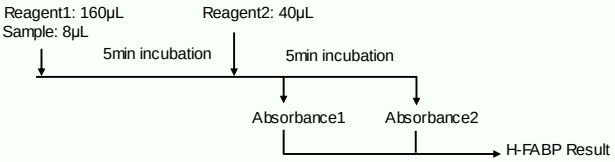


Figure-1

■Performance

Precision

When two distinct samples are determined 5 times simultaneously, the coefficient of variation in their concentration should be less than 10 %.

Accuracy

Control samples should show a value within ±10% of its known concentration with this reagent.

Correlative Test (LIBLIA vs ELISA)

Comparative performance studies were conducted using LIBLIA H-FABP and Markit™-M H-FABP (ELISA). 104 Serum samples, with H-FABP concentrations between 2.3 and 106.8 ng/mL were tested (Figure-2).

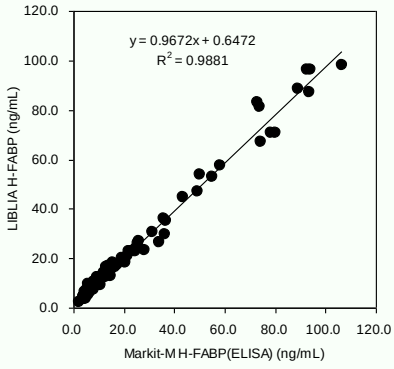


Figure-2

■References

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