

A rapid H-FABP test for qualitative measurement of H-FABP in serum, plasma and whole blood.

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Background: Human cardiac FABP ("**H-FABP**") is one of the most abundant proteins found in cardiomyocytes. H-FABP is mainly responsible for the transport of fatty acids. In the event of an acute myocardial infarction ("**AMI**"), the concentration of H-FABP in blood rises within 1-3 hours and returns to normal after 24 hours. Therefore, H-FABP is clinically useful as an early biomarker of AMI. According to industry literature, 99% of normal populations have an H-FABP level below 6 ng/mL. An increased level of FABP in circulation correlates with an increased risk of cardiac muscle damage. Early diagnosis is important because timely treatment of an AMI significantly improves the prognosis of a patient. An easy-to-use rapid test for the detection of H-FABP can facilitate an early diagnosis of an AMI. The objective of this study is to evaluate the performance of a new H-FABP rapid test.

Principle: The ADEXUS-Dx H-FABP Rapid Test ("**H-FABP Test**") is a solid phase immunochromatographic assay. The H-FABP Test uses a sandwich format to detect the presence of H-FABP above an established reference concentration in blood, plasma, and serum samples. The appearance of a purplish-red band in the test window indicates that the sample contains H-FABP above normal levels. The H-FABP Test has a unique feature of finger-stick, capillary whole blood sampling needing only 35 µl blood.

Performance: The H-FABP Test was negative to other forms of FABP, including liver-FABP, intestine-FABP, adipocyte-FABP, epidermal-FABP, ileal-FABP, brain-FABP. There is no hook effect at the highest H-FABP concentration present in patient serum (700 ng/ml). Sera containing human anti-mouse antibodies (HAMA) up to 327 ng/mL tested negative suggesting minimal interference by HAMA in a normal population based on the reference range for HAMA (0-188 ng/mL). The same test results were obtained for serum and plasma samples, the later of which were unaffected by anti-coagulants. A method comparison study between the H-FABP Test and the Randox quantitative assay showed the H-FABP Test cut-off was 6 ng/ml relative to Randox assay. The agreement between the two assays [for samples with H-FABP concentrations] is: 100% [below 1.5ng/mL]; 80% [1.5-3ng/mL]; 52% [3-12 ng/mL]; 73% [12-18 ng/mL]; and, 100% [above 18 ng/mL]. The discrepancies are likely due to the different antibodies used in the H-FABP Rapid Test and the Randox assay.

Conclusion: The H-FABP Test is a one-step rapid test with demonstrated specificity to cardiac FABP. It has a cut-off at 6 ng/ml based on comparison with the Randox assay, a generally acceptable clinical reference value for H-FABP. Therefore the H-FABP Rapid Test is a useful test for the early detection of AMI.