Instruction For Use

【Product Name】

H-FABP STAT (eCLIA)

【Order Information】

REF NO.	Package Size
0320511201	50T
0320511202	2×50T
0320511203	100T
0320511204	2×100T

【Intended Use】

Immunoassay for the in vitro quantitative determination of Heart-type Fatty Acid Binding Protein (H-FABP) in human serum and plasma. Determination of H-FABP is used for the auxiliary diagnosis of acute myocardial infarction.

【Summary】

The results show that H-FABP can be used as a new marker of myocardial injury, which is mainly used to assist the diagnosis and prognosis of acute myocardial infarction[1-2]. High concentration of H-FABP can promote cell apoptosis, which can be used as an indicator to predict heart failure. Detection of H-FABP concentration in patients with acute myocardial infarction (AMI) can help to understand the degree of myocardial damage, which is of great value for early active intervention in high-risk patients to improve their prognosis[3].

【Test Principle】

Sandwich principle. Total duration of assay: 9 minutes.

15μL of sample, a biotinylated monoclonal antibody, and a monoclonal antibody labeled with ruthenium complex form a sandwich complex. After addition of streptavidin-coated microparticles, the complex becomes bound to the solid phase via interaction of biotin and streptavidin. The reaction mixture is aspirated into the measuring cell where the microparticles are magnetically captured onto the surface of the electrode. Unbound substances are then removed with system reagent. Application of a voltage to the electrode then induces chemiluminescent emission which is measured by a photomultiplier. Results are determined via a calibration curve which is instrument specifically generated by 2-point calibration and a master curve provided via the RFID.

【Main Components】

The reagent pack consists of MB, RA, RB, calibrators and control materials(Optional). Different lots cannot be used at the same time or mixed up together.

Components	Ingredients	Volume (2×50T)	Volume (50T)	Volume (100T)	Volume (2×100T)
MB	Streptavidin-coated microparticles 0.75 mg/mL; 0.1M PBS, 0.05% ProClin300	2×1.8 mL	1×1.8 mL	1×3.5 mL	2×3.5 mL
RB	Biotinylated monoclonal H-FABP antibody 1.5 mg/L; 0.1M PBS, 0.1% ProClin300	2×3.8 mL	1×3.8 mL	1×7.5 mL	2×7.5 mL
RA	Monoclonal H-FABP antibodies labeled with ruthenium 1.5 mg/L; 0.1M PBS, 0.1% ProClin300	2×3.8 mL	1×3.8 mL	1×7.5 mL	2×7.5 mL
Calibrators	H-FABP antigen，bovine serum , preservative	High: 1×1.0 mL Low: 1×1.0 mL			
Control Materials (Optional)	H-FABP antigen，bovine serum , preservative	High: 1×1.0 mL Low: 1×1.0 mL			

Traceability: This method can be traced to manufacturer's selected measurement procedures.

See the control material value sheet for the target values and ranges of control materials.

Supporting instruments and materials required but not provided in this pack (provided by Lifotronic)

Additional materials for Automated ECL Immunoassay Analyzer eCL8000, eCL8000i, eCL8000p, eCL8000x:

- REF 679005, Auffer, 480 mL, or REF 679004, Auffer, 6×480 mL
- REF 679007, Buffer, 480 mL, or REF 679006, Buffer, 6×480 mL
- REF 679009, Concentrated Washing Buffer, 1 L, or REF 679008, Concentrated Washing Buffer, 6×1 L
- REF 679011, Assay Cup, 300 T, or REF 679012, Assay Cup, 3000 T

Additional materials for Automated ECL Immunoassay Analyzer eCL8600, eCL8600i, eCL8600p, eCL8800, eCL8800i, eCL8800p:

- REF 0320501804, Auffer, 2×1 L, or REF 0320501805, Auffer, 4×1 L
- REF 0320501904, Buffer, 2×1 L, or REF 0320501905, Buffer, 4×1 L
- REF 0320507502, PreClean, 2×800 mL, or REF 0320507503, PreClean, 4×800 mL
- REF 0320510001, Assay Cup/Assay Tip, 6×6×105, or REF 032120111, Assay Cup/Assay Tip, 12×2×105

Additional materials for Automated ECL Immunoassay Analyzer eCL9000, eCL9600, eCL9900, eCL9900i:

- REF 0320501801, Auffer, 2×2 L, or REF 0320501806, Auffer, 4×2 L
- REF 0320501901, Buffer, 2×2 L, or REF 0320501906, Buffer, 4×2 L
- REF 0320510001, Assay Cup/Assay Tip, 6×6×105, or REF 0320510002, Assay Cup/Assay Tip, 1×6×105.

【Storage and Shelf Life】

Store at 2℃-8℃.

Do not freeze.

Store the reagent kit upright in order to ensure complete availability of the microparticles during automatic mixing prior to use.

Damaged, expired or contaminated reagents should be discarded.

Stability of the reagents	
Unopened store at 2℃~8℃	18 months
Store at 2℃~8℃ after opening	8 weeks
Store on the analyzers at 2℃~15℃	8 weeks

The calibrators and control materials are stable up to the stated expiration date.

Stability of the calibrators and control materials	
Unopened store at 2℃~8℃	18 months
Store at 2℃~8℃ after opening	8 days

【Applicable Instrument】

Automated ECL Immunoassay Analyzers: eCL8000, eCL8000i, eCL8000p, eCL8000x, eCL8600, eCL8600i, eCL8600p, eCL8800, eCL8800i, eCL8800p, eCL9000, eCL9600, eCL9900, eCL9900i.

【Specimen collection, handling and storage】

Human serum samples or EDTA-K3, EDTA-K2, heparin lithium, heparin sodium anticoagulant plasma samples collected using blood vessels are recommended. Blood samples should be collected by standard operation of venous puncture; after complete coagulation, the tangible component should be removed by centrifugation. The sample should avoid bubbling during testing. Lipid layer floating on the upper of the sample should be removed. Samples with severe hemolysis are not in suggestion. Samples can be stored for 6 hours at 18℃-28 ℃, 7 days at 2℃-8 ℃, 3 months at -15℃ or lower than -15℃. Freezing and thawing cycle is permitted only once.

【Assay Procedure】

Testing procedures and precautions

Previous to operation, one should read the operational manual carefully to obtain system operation procedure, sample processing, security precaution, maintenance and other related information.

Set up H-FABP STAT test according to the operational manual.

Put the H-FABP STAT rackpack into the correct analyzer slot to automatically suspend magnetic beads at least 30 minutes before testing..

Recommended ambient temperature:10~30°C; Relative humidity: ≤ 80%.

Calibration

Calibration should be performed using lot-matching reagent and calibrators.

Before calibration, the reagent and main curve information should be imported into the analyzer via radio frequency identification reagent card (refer to instrument user manual). The analyzer adjusts the main curve to produce working curve according to the calibrator results, and identifies validity of the working curve automatically.

Recalibration is recommended when:

(1) The reagents of different lot are used;

(2) The same lot of reagents were used on the analyzer beyond 28 days;

(3) Quality control findings outside the defined limits;

(4) The Buffer of different losts are used.

Quality control

For quality control, use H-FABP STAT Control Materials.

In addition, other suitable control material can be used.

Control materials for the various concentration ranges should be run individually at least once every 24 hours when the test is in use, once per reagent kit, and following each calibration.

The control intervals and limits should be adapted to each laboratory's individual requirements. Values obtained should fall within the defined limits. Each laboratory should establish corrective measures to be taken if values fall outside the defined limits.

If necessary, repeat the measurement of the samples is concerned.

Follow the applicable government regulations and local guidelines for quality control.

Please make sure that the correct values are used.

Calculation

The system software automatically calculates the analyte concentration using particular algorithm, and the result unit is ng/mL or μg/L.1 ng/mL=1 μg/L.

Sample dilution

Samples with H-FABP concentrations above the detection range can be diluted with sample diluents. It is recommended to dilute by 1:10 (by instrumental automatic dilution or manual dilution). If diluted by hand, the result should be multiplied by the dilution multiple. If the instrument automatically dilutes, the instrument automatically calculates the result.

【Reference intervals】

By testing the serum samples from 300 healthy individuals (including 145 males and 155 females), The 95% upper limit of the reference interval is 6.596 ng/mL.

Due to differences in the region, race, gender and age, laboratories are recommended to set up their own reference ranges. Each laboratory should investigate the transferability of the expected values to its own patient population and if necessary determine its own reference ranges.

【Result Interpretation】

For explaining the result, the patient's overall clinical manifestation should be referred to, including symptoms, medical history and other relevant data and information.

【Limitations】

Test results are used only for clinical reference and cannot be used as the basis for diagnosis or rule-out of diseases alone. For diagnostic purposes, the results should always be assessed in conjunction with the patient's medical history, clinical examination and other findings.

When the sample containing bilirubin ≤ 75 mg/dL, hemoglobin ≤ 200 mg/dL, triglyceride ≤ 2500 mg/dL, biotin ≤ 30 ng/mL, HAMA ≤120 ng/mL, the interference deviation of the measured results is within ±10%. When the concentration of rheumatoid factor in the sample ≤ 1500 IU/mL, the relative recovery of the test results is between 90% and 110%.

When the H-FABP concentration reaches 1000 ng/mL, no hook effect was observed.

【Measuring Range】

The measuring range of the kit is 0.05~100 ng/mL. Values below the lower detection limit are reported as < 0.05 ng/mL. Values above the measuring range are reported as > 100 ng/mL (or up to 1000 ng/mL for 10 times diluted).

【Analytical Performance Charateristics】

Lower limits of measurement

Limit of Blank = 0.05 ng/mL

Limit of Detection = 0.1 ng/mL.

Accuracy

The relative deviation shall not exceed ±10%.

Linearity

The correlation coefficient is not less than 0.9900 in the interval of 0.1~100 ng/mL.

Within-run precision (repeatability)

The coefficient of variation (CV) ≤ 8%.

Between-lot precision

The coefficient of variation (CV) ≤ 10%.

Homogeneity of calibrators and control materials

Within-bottle homogeneity: The coefficient of variation (CV) ≤ 8%.

Method comparison

A comparison of the Lifotronic H-FABP STAT assay (y) with the commercial H-FABP (x) using clinical samples gave the following correlations:

Number of serum samples measured: 135

Linear regression:

y=0.9990x+0.5318

r = 0.998

The sample concentrations were between 0.94 and 94.64 ng/mL.

【Precautions and Warnings】

The kit is only used for in vitro diagnostics.

When using the kit, it's necessary to exercise the normal precautions in the laboratory.

All reagents and samples including specimen, calibrators and control materials, should avoid foaming before and during test.

Test results of the kit are for clinical reference only, and clinical evaluation of patients should be combined with their symptoms and signs, medical history, other laboratory examination results and treatment responses.

Due to factors such as methodology or antibody specificity, testing identical samples with reagents from different manufacturers may get different results, and the results from different kits should not compare directly, lest cause the wrong medical explanation. It's suggested that laboratorians should point out the characteristics of used reagent in the test report to the clinician. In serial monitoring, if the reagent type is changed, a continuous parallel test should be performed and comparison of the results to the former should be to determine new baseline value.

This product contains animal-sourced materials and may have potential biological risk. All samples and test wastes should be treated as the source of infection, and all wastes must be disposed according to local regulations.

Any serious incident that would be occurred in relation to the device shall be reported to the manufacturer and the competent authority of the Member State in which the user and/or the patient is established.

The preservative ProClin™300 which contain Mixture of 5-Chloro-2-methyl-4-isothiazolin-3-one and 2-Methyl-2H-isothiazol-3-one (3:1), May cause an allergic skin reaction. If skin irritation or rash occurs: get medical advice/attention, take off contaminated clothing and wash it before reuse, and Dispose of contents/container to an approved waste disposal plant.

【Bibliography】

1. CHAN C P, SUM K W, CHENG K Y, et al. Development of a quantitative lateral-flow assay for rapid detection of fatty acid-binding protein[J]. Journal of Immunological Methods, 2003, 279(1-2): 91-100.
2. CAVUS U, COSKUN F, YAVUZ B, et al. Heart-type fatty-acid binding protein can be a diagnostic marker in acute coronary syndrome[J]. J Natl Med Assoc, 2006;98(7): 1067-1070.
3. Kilculle N, Viswanathan K, Das R, et al. Heart type fatty acid binging protein predicts long term mortality after acute coronary syndrome and identifies high risk patients across the range of troponin values. J Am Coll Cardiol, 2007,50(21):2061-2067.

【Symbols Explanation】

Symbol	Title of Symbol	Symbol	Title of Symbol
	Manufacturer		Consult instructions for use
	Use-by date	IVD	In vitro diagnostic medical device
LOT	Batch code		Sufficient for <n> tests
SN	Serial number		Biological risks
	Temperature limit		This way up
EC REP	Authorized representative in the European Community	CE	Indicates this device is in compliance with Europe Directive.
REF	Catalogue number	P/N	Material code
	Warning		Date of manufacture
UDI	Unique device identifier		

【Manufacturer】

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【Version and Revision】

Version: 2.0

Issue Date: 2025-03-04