Instruction For Use

【Product Name】

Heart-type Fatty Acid Binding Protein (Electrochemiluminescence Immunoassay)

【Order Information】

REF NO.	Package Size
691023	100T
691024	2×100T
691025	50T
691026	2×50T

【Intended Use】

Immunoassay for in vitro quantitative determination of H-FABP in human serum and plasma. Clinically used for the auxiliary diagnosis of acute myocardial infarction.

Heart-type fatty acid binding protein(H-FABP) is a 15KD cytoplasmic protein abundant in cardiomyocytes. The kinetics are similar to myoglobin, which begins to rise after 2-3 hours after chest pain. Return to normal levels within 24 hours and reach the highest value within 4-8 hours; and H-FABP is immune to other types of FABP, specific, and does not cross-react. H-FABP has many advantages in the role of AMI after early diagnosis, monitoring secondary MI, and assessing MI area. Based on the above characteristics, H-FABP is an ideal early diagnosis index for acute myocardial infarction (AMI).[1-3]

【Test Principle】

Sandwich principle. Total duration of assay: 18 minutes.

1st incubation: 15 μL of sample, biotinylated monoclonal H-FABP-specific antibody and monoclonal H-FABP-specific antibody labeled by ruthenium trisbipyidyl NHS ester form a sandwich compound by immunoreaction.

2nd incubation: After addition of streptavidin-coated micro magnetic beads, the compounds bind to the micro beads via interaction of biotin and streptavidin.

Measurement: The reaction mixture is aspirated into the measuring cell where the micro beads and immuno-compounds are magnetically captured onto the surface of the electrode.

Unbound substances are then removed by Buffer. Application of a voltage to the electrode then induces emission of luminescence which is measured by a photomultiplier.

Results are determined via calibration and a master curve provided via the reagent barcode.

【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 (50T)	Volume (2×50T)	Volume (100T)	Volume (2×100T
(MB)	Streptavidin-coated micro magnetic beads: preservative	1×3.0 mL	2×3.0 mL	1×5.0 mL	2×5.0 mL
(RB)	Anti-H-FABP-Ab~biotin: 0.1 M PBS; preservative	1×3.8 mL	2×3.8 mL	1×7.5 mL	2×7.5 mL
(RA)	Anti-H-FABP-Ab~Ru(bpy)$^{2+}_{3}$,: 0.1 M PBS; preservative	1×3.8 mL	2×3.8 mL	1×7.5 mL	2×7.5 mL
Calibrators	Bovine serum , preservative	High: 1×1.0 mL; Low: 1×1.0 mL			
Control Materials (Optional)	Bovine serum , preservative	High: 1×1.0 mL; Low: 1×1.0 mL			

Traceability: This method can be traceable to enterprise 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 0320507501, PreClean, 2×2 L, or REF 0320507504, PreClean, 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 at 2℃~8℃	18 months
Store at 2℃~8℃ after opening	8 weeks
Stored 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 weeks

【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】

It is recommended to use serum samples or plasma samples collected from EDTA and heparin anticoagulant blood collection tubes.

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 would better to be tested in 6 hours after collection, otherwise, should be stored 2~8℃ for no more than 7 days or -25~-15℃ for 3 months. Freezing and thawing cycle is permitted only once.

【Assay Procedure】

Testing procedures and precautions

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

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

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

Recommended ambient temperature:10~30℃; 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 (RFID) 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 4 weeks;

(3) Quality control misses the target.

(4)The Buffer of different lots are used.

Quality control

For quality control, use H-FABP 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 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.

Specimen dilution

Samples with H-FABP concentrations above the measuring range would be manually diluted with H-FABP-negative serum.

The recommended dilution ratio is 1:10. After manual dilution, multiply the result

by the dilution factor.

【Biological reference interval】

According to serum test results of 285 healthy human (males 140, females 145) , the percentile 95 gives the reference range of < 6.592 ng/mL.

Due to differences in the region, race, gender and age, laboratories are recommended to set up their 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.

The measuring range of the kit is 0.1~100 ng/mL. For samples with H-FABP contents below the lower detection limit, the results are reported in < 0.10 ng/mL. If the H-FABP contents is above the upper detection limit, then the sample should be diluted and re-tested. The results are reported after multiplying with the dilution factor.

There is no high-dose hook effect at H-FABP concentrations 1000 ng/mL.

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

【Analytical Performance】

Lower Limits of measurement

Lower detection limit is 0.10 ng/mL.

Accuracy

When measuring the appropriate concentration of the added sample, the recovery rate should be in the range of 90% to 110% or measuring the metrologically traceable accuracy control materials, the ratio between resulting value and target value lies between 0.900 and 1.100.

Linearity

The correlation coefficient (Pearson's r) is not less than 0.9900 in the interval of 0.50~100 ng/mL.

Within-run precision (repeatability)

The coefficient of variation (CV) is less than 8%.

Between-lot precision

The coefficient of variation (CV) is less than 10%.

Homogeneity of calibrators and control materials

Within-bottle homogeneity: coefficient of variation (CV) ≤10%.
Between-bottle homogeneity: coefficient of variation (CV) ≤10%.

Method comparison

A comparison of the Lifotronic H-FABP assay (y) with the commercial H-FABP reagent kit (x) using clinical samples gave the following correlations:
Number of plasma samples measured: 180
Linear regression:
y=0.1647+1.005x
r = 0.9873
The sample concentrations were between 0.65 and 89.51 ng/mL.

【Precaution and Warning】

The kit is only used for in vitro diagnostics.

Exercise the normal precautions required for handling all laboratory reagents.

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

Disposal of all waste material should be in accordance with local guidelines.

Safety data sheet available for professional user on request.

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. thus, proper personal protection should be adopt while handling the reagent: avoid breathing dust/fume/gas/mist/vapours/ spray, wear protective gloves and contaminated work clothing should not be allowed out of the workplace. 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.

【Symbols Explanation】

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

【Literature References】

1. Burtis CA, Ashwood ER, Editors. Tietz Textbook of Clinical Chemistry. 3rd ed[M]. Philadelphia: WB Saunders Company ,1999.
2. Tambara K, Fujita M,Miyamoto S, et al, Pericardial fluid level of heart-type cytoplasmic fatty acid-binding protein (H-FABP) is an indicator of severe myocardial ischemia[J]. Int J Cardiol, 2004, 93(2/3): 281-284.
3. Nayashida N,Chihara S, Tayama E, et al. Influence of renal function on serum and urinary heart fatty acid-binding pmteion levels[J]. J Cardiovasc Surg (Torino), 2001, 42(6): 735-740.

【Manufacturer】

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