Heart-type Fatty Acid-Binding Protein Assay Kit (H-FABP)

Method: Immunoturbidimetric Method

Cat . No.	Package Size	Analyzer
EGS4281X	R1:1×60 ml R2:1×15 ml	For Hitachi 917 Olympus AU640/400/600
EGB4280X	R1:1×60 ml R2:1×15 ml	For Hitachi 717 ShimadzuCL7200/8000
EGH4281X	R1:1×40 ml R2:1×10 ml	For Hitachi 902
EGD4281X	R1:24×3.8 ml R2:6×3.8 ml	For Siemens Dupont/Siemens Behring Series
EGFABP460	R1: 1×20 ml R2: 1×5ml	For Mindray BS120/180/190/200/220/230/240/430/460/830

INTENDED USE

For in vitro quantitative determination of heart-type fatty acid-binding protein in human serum or plasma.

CLINICAL SIGNIFICANCE

Fatty acid-binding proteins (FABP) are a class of cytoplasmic proteins that bind long chain fatty acids. FABP are small intracellular proteins (~13-14 kDa) with a high degree of tissue specificity. They are abundantly present in various cell types and play an important role in the intracellular utilization of fatty acids, transport and metabolism. There are at least nine distinct types of FABP, each showing a specific pattern of tissue expression. Due to its small size, FABP leaks rapidly out of ischemically damaged necrotic cells leading to a rise in serum levels. Ischemically damaged tissues are characterized histologically by absence (or low presence) of FABP facilitating recognition of such areas. Following acute myocardial infarction (AMI) the small protein H-FABP is rapidly released into the circulation. So H-FABP is a sensitive new AMI marker.

ASSAY PRINCIPLE

Sample is reacted with a buffer and anti-FABP coated latex. The formation of the antibody-antigen complex during the reaction results in an increase in turbidity, the extent of which is measured as the amount of light absorbed at 700nm. By constructing a standard curve from the absorbance of the standards, H-FABP concentration of sample can be determined.

REAGENT COMPOSITION

Contents	
Reagent 1 (R1)	
Bovine serum protein Preservative	1% 0.05%
Reagent 2 (R2)	
Latex particles of monoclonal antibody (mouse) against human heart type fatty acid binding protein Stabilizer Preservative	0.15% 5% 0.05%

STABILITY AND PREPARATION OF REAGENTS

1. Stable up to the expiry date when the reagent is sealed and stored in dark at 2-8 ℃.
2. Reagents should not be frozen.
3. Do not mix reagents of different batches.
4.The production date and expiry date are shown on the label.
5.Once opened, the reagents are stable for 28 days when refrigerated on the analyzer or refrigerator.
6.Reagents should not be contaminated.

APPLICABLE INSTRUMENT

This kit is theoretically suitable for all biochemistry analyzers and spectrophotometers covering the wavelength range of 700nm.
It is recommended to use this kit on a biochemistry analyzer for testing according to laboratory conditions.

SAMPLE COLLECTION AND PREPARATION

Use fresh patient serum or plasma samples.

Serum samples are stable for 7 days at 2-8℃.

ASSAY PROCEDURE

Reagent preparation: reagent is ready to use.
Test Condition(Hitachi 917)

Main wavelength	700nm	Sample(S)	8 μl
Secondary wavelength	-	Reagent 1(R1)	160μl
Reaction temperature	37℃	Reagent 2(R2)	40μl
Cuvette diameter	1cm	Reaction type	Two-point end method

Operate procedure

Add into cuvette:	
Sample(S)	8μl
Reagent 1(R1)	160μl
Mix well and incubate for 5 minutes at 37℃	
Reagent 2(R2)	40μl
Add 40 μl R2 into cuvette, mix well and incubate for 30 secs at 37℃, measure the original absorbance A1 at 700 nm. Continue incubate for 270 secs, read final absorbance A2 . Calculate △A=A2-A1	

Note: Parameters above are only introduced with Hitachi 917 as an example. The parameters of different biochemistry analyzers are slightly different. Please read the manual carefully before setting parameters.

CALIBRATION

It is recommended to use Gcell H-FABP calibrator.
Calibrator traces to the company working calibrator.
1. According to the requirements of the calibration procedure in the operation manual of biochemistry analyzer, each laboratory establishes its own calibration procedure according to the specific conditions.
2 Requirements for calibration and frequency: It is recommended to calibrate at least once every two weeks. When the following situations occur, it is recommended to re-calibrate: change the reagent batch number, the indoor quality control runs out of control, the biochemistry analyzer carries out major maintenance or replaces the main parts such as light source or cuvette.

QUALITY CONTROL

Beijing Strong Biotechnologies, Inc.
Add: 5/F,KuangYi Building,No.15,Hua Yuan Dong Lu,Haidian District,Beijing 100191,P.R.China
Tel: +86 10 8201 2486 Fax: +86 10 8201 2812
Web: http://en.bsbe.com.cn/ Email:overseas@bsbe.com.cn

For quality control, use Gcell FABP control as daily quality control serum and can be purchased separately. Values should fall within a specific range. If these values fall outside the range and repetition excludes error, the following steps should be taken:
1 Check the parameter setting and light source.
2 Check the cleanliness of the cuvette and sampling needle.
3 Check whether water is contaminated or not. Bacterial growth can lead to incorrect results.
4 Check the reaction temperature.
5 Check the validity of the kit.

CALCULATION OF RESULT

Setting calibration curve by calibrator concentrations against the corresponding ΔA values. The concentration of H-FABP in the sample is obtained by ΔA value read from the calibration curve.

REFERENCE RANGE

Normally serum or plasma: < 5ng/mL.
Laboratories are suggested to establish its own reference interval according to age, sex, diet and region.

INTERFERENCE

The effect of Hemoglobin≤ 500 mg/dl, Bilirubin≤ 19.4 mg/dl, Intralipid≤ 500 mg/dl, RF≤ 500 IU/ml, is less than 10%.

ACCURACY

Compared with competitors, in the range of [2.5, 130] ng / ml, the correlation coefficient R ≥ 0.975, the absolute deviation measured in the range of [2.5, 50] ng / ml should ≤± 5ng / ml, and the relative deviation measured in the range of (50, 130] ng / ml should ≤± 10%.

SENSITIVITY

When the sample concentration is 20.0ng/mL, the absorbance change should ≥ 0.0100.

LINEARITY

In the range of [2.5, 130] ng/ml,the correlation of linearity is ≥0.990. In the range of [2.5, 50] ng/ml, the absolute deviation of linearity is ±5ng/ml and between (50, 130] ng/ml, the relative deviation of linearity is ≤ ± 10%.

PRECISION

Repeatability precision was obtained by testing control or sample for 20 times of repeated measurement. Intermediate precision was obtained by testing human samples or control for 2 batches per day, and each batch was measured for 2 times separately in morning and afternoon, for total 20 days. The results are as follows:

A)Repeatability (N=20)

	Mean(ng/mL)	CV(%)
Level1	6.89	3.28
Level 2	26.57	1.83

B)Intermediate precision (N=80)

	Mean(ng/mL)	CV(%)
Level1	8.10	2.06
Level 2	31.51	3.17
Sample1	15.26	1.70

SAFETY PRECAUTIONS AND WARNINGS

1. Calibration is required for each determination, and different reagent batch numbers should be calibrated again.
2. This reagent contains antibody raw materials. If it is splashed on the skin surface in use, please rinse it with water.
3. According to the requirements of different instruments, the dosage of reagents and samples can be changed in proportion.
4. When using the reagent, pour the reagent into the clean container according to the actual dosage, avoid repeatedly pouring in and out. Put the reagent into the refrigerator immediately after the reagent bottle is closed.
5. The calibrator and quality control materials are based on human matrix serum. The HIV (HIV1, hiv2) antibody, hepatitis B surface antigen (HBsAg) and hepatitis C virus (HCV) antibodies have been tested, and the results are negative. Although the detection method is highly accurate, it can not guarantee that all infected donors can be found. Therefore, the quality control samples should be treated as infectious samples.

REFERENCES

1. Liao J, Chan CP, Cheung YC, Lu JH, Luo Y, Cautherley GW,Glatz JF, Renneberg R. Human heart-type fatty acid-binding protein for on-site diagnosis of early acute myocardial
2. Kilcullen et al. Heart-type fatty acid-binding protein predicts
long-term mortality after acute coronary syndrome and identifies high-risk patients across the range of troponin
3. O'Donoghue M, de Lemos JA, Morrow DA, Murphy SA,
Buros JL, Cannon CP, Sabatine MS. Prognostic utility of heart-type fatty acid binding protein in patients with acute
coronary syndromes. Circulation. 2006 Aug 8;114(6):550-7
4. Han Zhijun, Huang Zhifeng, et al. Automatic analysis of common items in clinical chemistry. Liaoning: Liaoning science and Technology Press, 2005: 1113

INDEX OF SYMBOLS

	Manufacture
REF	Catalogue Number
LOT	Lot number
	Date of manufacture
	Use by(Expiration date)
IVD	For In-Vitro Diagnostic use only
2℃ 8℃	Stored at 2-8℃
	Attention:See instruction for use
EC REP	Authorized Representative in the European Company

Beijing Strong Biotechnologies, Inc.
Add: 5/F,KuangYi Building,No.15,Hua Yuan Dong Lu,Haidian District,Beijing 100191,P.R.China
Tel: +86 10 8201 2486 Fax: +86 10 8201 2812
Web: http://en.bsbe.com.cn/ Email:overseas@bsbe.com.cn