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

Method: Immunoturbidimetric

Cat . No.	Size	Instrument
GS281X	R1:1×15 ml R2:1×15 ml	For Hitachi 7170/7180& Olympus AU640/400/600
GB280X	R1:1×15 ml R2:1×15 ml	For Hitachi 7060/7150& ShimadzuCL7200/8000
GT281X	R1:1×15 ml R2:1×15 ml	For TOSHIBA serials
GH281X	R1:1×15 ml R2:1×15 ml	For Hitachi 7020
GD281X	R1:18×3.8 ml R2:18×3.8 ml	For Dupont

INTENDED USE

For the quantitative determination of human H-FABP in serum and plasma by immunoturbidimetric assay. For in vitro diagnostic use only.

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	Tris-buffer solution
Reagent 2	Suspension of anti-human H-FABP antibody coated with latex particles

SAMPLE COLLECTION AND PREPARATION

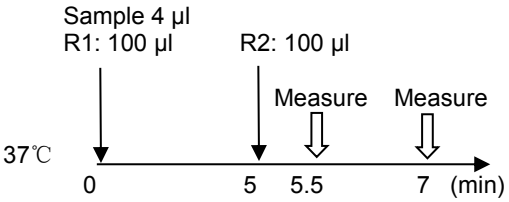
Use fresh patient serum or plasma samples.
Serum samples are stable for 6 days at 4℃.

STABILITY AND PREPARATION OF REAGENTS

Ready to use.
Stable up to the expiry date when stored at 2-8℃.

ASSAY PROCEDURE

Test Procedure for Analyzers (HITACHI 7180)
Assay Mode: 2 Point End 19-23
Wave length (main): 700nm



1. Mix 4 µl sample with 100 µl R1 and incubate at 37℃ for 5 minutes.
2. Add 100 µl R2 into cuvette, mix and incubate for 30 seconds at 37℃.
3. Read initial absorbance A_1 and incubate for another 1.5 minutes, read final absorbance A_2.
4. Calculate the absorbance change $\Delta A=A_2-A_1$.

CALIBRATION

Recommend using Gcell calibrator (Cat .No. GC-FABP).

CALCULATION

By constructing a standard curve from the absorbance of the standards, H-FABP concentration of sample can be determined. Do not attempt to extrapolate above or below the range of the calibrators.

QUALITY CONTROL

For quality control, use GQ-FABP 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 instrument settings and light source.
2. Check reaction temperature.
3. Check expiration date of kit and contents.

NORMAL VALUE

< 5ng/ml

It is recommended that each laboratory establishes its own reference range to reflect the age, sex, diet and geographical location of the population.

MAIN PERFORMANCE CHARACTERISTICS

LINEARITY

In the range of 2.5-130ng/ml,the correlation of linearity is ≥0.990. In the range of 2.5-50ng/ml, the deviation of linearity is ±5ng/ml and between 50-130ng/ml, the deviation of linearity is within ± 10%.

PRECISION

the CV of the test should be ≤ 5%

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CE For professional use Revised 01DEC11 version 0801

Intra assay precision			
N=20	Level 1	Level 2	Level 3
Mean (ng/ml)	5.38	17.62	30.47
SD	0.24	0.25	0.20
CV	4.46%	1.42%	0.66%

Inter assay precision			
N=5	Batch 1	Batch 2	Batch 3
Mean	17.77	17.62	17.82
$\bar{x}$	17.74		
(Xmax-Xmin)/ $\bar{x}$	(17.82-17.62)/17.74*100=1.12%		

INTERFERENCE

The following analytes concentration were not found to affect the assay:

Hemoglobin: up to 500 mg/dl
Bilirubin: up to 19.4 mg/dl
Triglycerides: up to 1500 mg/dl
RF: up to 500 IU/ml

SAFETY PRECAUTIONS AND WARNINGS

1. For *in vitro* diagnostic use only. Do not pipette by mouth. Exercise the normal precautions required for handing laboratory reagents.
2. Reagents contain Sodium Azide. Avoid ingestion or contact with skin or mucous membranes. In case of skin contact, flush affected area with copious amounts of water. In case of contact with eyes or if ingested, seek immediate medical attention.
3. Sodium Azide reacts with lead and copper plumbing, to form potentially explosive azides. When disposing of such reagents flush with large volumes of water to prevent azide build up. Exposed metal surfaces should be cleaned with 10% sodium hydroxide.
4. Specimens should be treated as potentially infectious(HIV, Hepatitis B virus, Hepatitis C virus, etc.) and handled with appropriate caution.
5. Reagents with different lot numbers should not be interchanged or mixed.

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.

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

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