Ischemia modified albumin Assay Kit (IMA)

Method: Albumin-cobalt Binding

Cat . No.	Size	Instrument
GS271X	R1:1×60 ml R2:1×20 ml	For Hitachi 7170/7180& Olympus AU640/400/600
GB270X	R1:1×60ml R2:1×20ml	For Hitachi 7060/7150& ShimadzuCL7200/8000
GX271X	R1:1×60ml R2:1×20 ml	For Beckman

INTENDED USE

For the *in vitro* quantitative determination of Ischemia modified albumin in serum.

CLINICAL SIGNIFICANCE

Ischemia modified albumin is produced when N-terminal amino acid of albumin is modified by copper ion or others. This situation occurs when a tissue is ischemia or reperfusion occurs. IMA is a early warning indicator before cell necrosis occurs in myocardical ischemia.The elevation degree can indicate the degree of myocardical ischemia. In clinic, IMA is a potential use in early diagnosis for acute myocardic ischemia(AMI) and acute coronary syndromes(ACS).

ASSAY PRINCIPLE

After IMA in sample conjugates with cobalt ion, the color developing ragent conjugates with cobalt ion else to produce a red material.By the standard curve,calculate the IMA concentration in sample.

REAGENT COMPOSITION

Contents	
R1	Tris/HCl buffer、$CoCl_2$、 Polyethylene Glycol、Nacl
R2	TDD、NaCl

SAMPLE COLLECTION AND PREPARATION

Fresh serum.

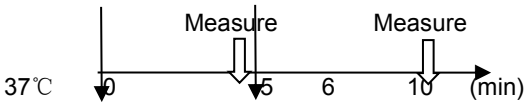
STABILITY AND PREPARATION OF REAGENTS

All reagents are 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 16-34

Wave length (sub/main): 700/505nm
Sample 20 µl
R1: 150µl R2: 50 µl



CALIBRATION

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

CALCULATIONS OF RESULTS

Plot calibrator concentrations against the corresponding ΔA values using graph paper. The concentration of IMA in the sample is obtained by reading of a value from the calibration curve. Do not attempt to extrapolate above or below the range of the calibrators.

QUALITY CONTROL

For quality control, use Gcell GQ-IMA as daily quality control 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

< 78.1U/ml
It is recommended that each laboratory should establish its own normal range to reflect the age, sex, diet and geographical location of the population.

MAIN PERFORMANCE CHARACTERISTICS

LINEARITY

In the range of 20 ~ 100 U/ml , the linear correlation coefficient r ≥ 0.990. In the range of 20 ~ 50 U/ml (containing 50 U/ml), linearity deviation shall not exceed ± 3 U/ml. Between 50 ~ 100 U/ml, the linear deviation should not exceed ± 10%.

PRECISION

The CV of the test should be ≤ 10%.

Intar assay precision		
N=20	level 1	level 2
Mean(U/ml)	49.7	49.7
SD	0.44	0.44
CV(%)	0.89	0.89

Inter assay precision			
N=5	Batch 1	Batch 2	Batch 3

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Mean(U/ml)	48.8	47.8	49.3
$\bar{x}$	48.60		
(Xmax-Xmin)/$\bar{x}$	(49.3-47.8)/48.6*100=3.04%		

INTERFERENCE

The following analytes were tested up to the levels indicated and found not to interfere:

Ascorbic acid: up to 50 mg/dl
Bilirubin: up to 40 mg/dl
Hemoglobin: up to 200 mg/dl
Intralipid: up to 600mg/dl
Heparin: up to 100U/ml

SAFETY PRECAUTIONS AND WARNINGS

1. For in vitro diagnostic use only. Do not pipette by mouth. Exercise the normal precautions required for handling laboratory reagents.
2. Reagent contains 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 from building 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. Bar-Or, D., et al., Characterization of the Co^{2+} and Ni^{2+} binding amino-acid residues of the N-terminus of human albumin. European Journal of Biochemistry, 2001. 268(1): p. 42-48.
2. Sinha, M.K., et al., Ischemia modified albumin is a sensitive marker of myocardial ischemia after percutaneous coronary intervention. Circulation, 2003. 107(19): p. 2403.
3. Bar–Or, D., E. Lau, and J.V. Winkler, A novel assay for cobalt-albumin binding and its potential as a marker for myocardial ischemia—a preliminary report. The Journal of emergency medicine, 2000. 19(4): p. 311-315.

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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