ApolipoproteinA1 Assay Kit (APOA1)

Method: Immunoturbidimetric

Cat .No.	Size	Instrument
GB160Z	R1: 4×45 ml R2: 4×15 ml	For Hitachi 717 &ShimadzuCL7200/8000
GS161Z	R1: 3×60 ml R2: 3×20 ml	For Hitachi917 &OlympusAU640/400/600
GB160Z/S	R1: 1×45 ml R2: 1×15 ml	For Hitachi 717 &ShimadzuCL7200/8000
GS161Z/S	R1: 1×60 ml R2: 1×20 ml	For Hitachi917 &OlympusAU640/400/600
GX161Z/S	R1: 1×60 ml R2: 1×20 ml	For SYNCHRON CX4-5-7-9/LX20/DXC600-800
GX161Z	R1: 2×60 ml R2: 2×20 ml	For SYNCHRON CX4-5-7-9/LX20/DXC600-800
GD161Z	R1: 24×3.8 ml R2: 12×2.6 ml	For DATE DIMENSION

INTENDED USE:

For the *in vitro* quantitative determination of apolipoprotein A Ⅰ (Apo A Ⅰ) in serum. For use as an aid if assessing the risk of coronary artery disease.

CLINICAL SIGNIFICANCE[1,2]

Lipids are metabolised in the intestine or liver, and are transported to tissues and organs after hydrophilic adaptation by a series of micellar structures. These structures consist of an outer monolayer of protein (an apolipoprotein) and polar lipids (phospholipids and unesterified cholesterol) plus an inner core of neutral lipids (triglycerides and cholesterol esters). The apolipoproteins interact with a series of enzymes and tissue receptors and are therefore responsible for further metabolism and catabolism of the micelle.

The A apolipoproteins are the main form of protein found in high density lipoproteins (HDL), although chylomicrons are also present. The main role of apolipoprotein A Ⅰ is in the activation of Lecithin cholesterol acyl transferase (LCAT) and removal of free cholesterol from extra-hepatic tissues. Apolipoprotein A Ⅰ may therefore be described as non-atherogenic, showing an inverse relationship to cardiovascular risk. Studies have shown that there is an inverse relationship between Apo A Ⅰ and coronary artery disease and a direct relationship with Apo B such that patients with CAD have generally reduced levels of Apo A Ⅰ and increased levels of Apo B.

PRINCIPLE[3]

This method is based on the reaction of a sample containing human Apo A Ⅰ and specific antiserum to form an insoluble complex which can be measured turbidimetrically at 340nm. By constructing a standard curve from the absorbances of standards the concentration of apo A Ⅰ can be determined.

REAGENT COMPOSITION

Contents	Concentrations
R1. Buffer	
Polyethylene glycol	maximum 4%
Tris/HCl buffer	15 mmol/l
Sodium Chloride	106 mmol/l
R2. Antibody Reagent	
Anti-human-apo A Ⅰ	

SAMPLE COLLECTION AND PREPARATION

Serum samples.

Apo A Ⅰ is stable for 7 days at 15 -25℃, 4 weeks at 2-8℃ or 2 months at - 20℃ （frozen once only).

STABILITY AND PREPARATION OF REAGENTS

Reagents are stable until expiry date when stored unopened at 2-8℃.

ASSAY PROCEDURE

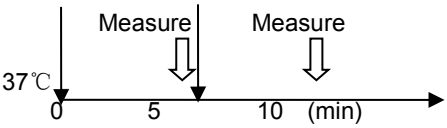
Test Procedure for Analyzers (Hitachi7180)

Assay Mode: 2 Point End 16-34

Wave length (sub/main): 700/340nm

Sample: 2 µl

R1: 225 µl R2: 75 µl



CALIBRATION[4]

Apolipoprotein Calibrator (value is lot specific) is recommended for calibration.

Recalibration is recommended for each series of samples run. The level of the calibrator was determined using a WHO / IFCC reference standard[5,6].

CALCULATIONS OF RESULTS

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

QUALITY CONTROL

For accuracy and reproducibility control: Specific Protein Controls are recommended. Quality Control Assayed Multisera are recommended for daily quality control. One control should be assayed after every 10 samples. The values obtained for these Controls should fall within specified limits. If Control values fall outside the ranges and repetition of the assay provides the same results, thereby excluding technique 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.

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REFERENCE VALUE [7]

120 - 176 mg/dl
It is recommended that each laboratory should assign its own normal range as this is dependent upon geographical location.

SPECIFIC PERFORMANCE CHARACTERISTICS

LINEARITY

The assay is linear up to 239mg/dl.
Above this concentration, dilute the sample with NaCl solution (9 g/L sodium chloride in water) and repeat the assay.

PRECISION

The CV of the test should be less than 5%.

Intar assay precision		
N=20	level 1	level 2
Mean(mg/dl)	112.2	102.84
SD	0.91	1.34
CV(%)	0.81	1.31

Inter assay precision			
N=5	Batch 1	Batch 2	Batch 3
Mean(mg/dl)	114.7	114.9	112.7
$\bar{x}$	114.1		
(Xmax-Xmin)/$\bar{x}$	(114.9-112.7)/114.1*100=1.91%		

INTERFERENCE

The following analytes were tested up to the levels indicated and found not to interfere:
Intralipid: up to 500 mg/dl
Bilirubin: up to 40 mg/dl
Hemoglobin: up to 500 mg/dl

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

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2. Wang, X.L., et al Clin. Chem. 1989; 35(10): 2082-2086
3. Labeur, C., Shepherd. J., Rosseneu, M. Clin. Chem.1990; 36(4):591-597.
4. Adolphson, J.L., Albers J.J., Journal of Lipid Research 1989; 30:597-606
5. Marcinova, S.M, et al (1992), WHO/IFCC Meeting On Standardisation of Apolipoproteins, May 1992, Nice, France.
6. Albers, J.J, et al (1992) Clin Chem. 38:658.
7. Provisional normal values recalculated on the basis of the CDC values C. Fruchart, J-C. (1986), Ann. Biol. Clin. 44:116.
8. Kukita H., Hiwada K., Kobubu T. Serum Apolipoprotein A-1, A-2 and B levels and their discriminative values in relatives of patients with coronary artery disease. Atheroscler 51:261, 1984.

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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