Lipoprotein (a) Assay Kit
Lp(a)

Method: Immunoturbidimetric

Cat .No.	Size	Instrument
GB9150Z	R1: 3×40 ml R2: 1×30 ml	For Hitachi 717 &ShimadzuCL7200/8000
GS9151Z	R1: 2×60 ml R2: 2×15 ml	For Hitachi917 &OlympusAU640/400/600

INTENDED USE
For the *in vitro* quantitative determination of Lipoprotein (a) in serum or plasma.

CLINICAL SIGNIFICANCE
Lipoprotein (a) determination is intended for use in conjunction with clinical evaluation, patient risk assessment and other lipid tests to evaluate disorders of lipid metabolism and to assess coronary heart disease in specific populations.

ASSAY PRINCIPLE
Sample is reacted with a buffer and anti-Lp(a) 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 600 nm. By constructing a standard curve from the absorbance of the standards, Lp(a) concentration of sample can be determined.

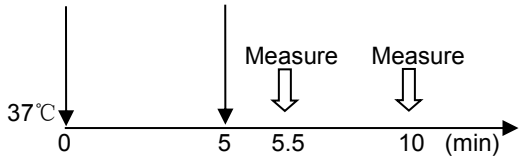
REAGENT COMPOSITION

Contents	
R1	Good's Buffer Solution
R2	Suspension of anti-human Lp (a) rabbit polyclonal antibodies coated latex particles

SAMPLE COLLECTION AND PREPARATION
Use fresh patient serum or heparin treated plasma samples.

STABILITY AND PREPARATION OF REAGENTS
All reagents are ready to use.
Stable up to the expiry date when stored at 2-8℃.
Once opened contents are stable for 1 month at 2-8℃.
The detailed term of validity sees product packing box.

ASSAY PROCEDURE
Test Procedure for Analyzers (Hitachi 7170/917)
Assay Mode: 2Point End, 19-34
Wave length (main/sub): 600nm
Sample 3 µl
R1: 280 µl R2: 70 µl



CALIBRATION
Recommend that this assay should be calibrated using Gcell Calibrator.

CALCULATION OF RESULTS
Plot calibrator concentrations against the corresponding ΔA values using graph paper. The concentration of Lp (a) 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 Lp (a) control as daily quality control sera 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
serum or plasma： ≤ 30mg/dl
Each laboratory should establish an expected range with a set of standards.

MAIN PERFORMANCE CHARACTERISTICS

LINEARITY
The method is linear up to a concentration of 100 mg/dl. If the concentration is above this limit,please dilute 1+1 with 0.9% NaCl and repeat assay. Multiply the result by 2.

PRECISION
The CV of the test should be ≤10%.

Intar assay precision		
N=20	level 1	level 2
Mean(mg/dl)	12.8	44.2
SD	0.58	0.90
CV(%)	4.55	2.03

Inter assay precision			
N=5	Batch 1	Batch 2	Batch 3
Mean(mg/dl)	44.5	44.5	44.1
$\bar{x}$	44.3		
(Xmax-Xmin)/$\bar{x}$	(44.5-44.1)/44.3*100=0.86%		

INTERFERENCE
The following analytes were tested up to the levels indicated and found not to interfere:
Hemoglobin: up to 1000 mg/dl
Bilirubin: up to 60 mg/dl
Triglycerides: up to 3000 mg/dl
Ascorbic acid: 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.

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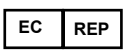
2. Reagent contains Sodium Azide. Avoid ingestion or contact with skin or mucous membranes. In case of skin contact, flush affected area with copious amounts of water. In case of contact with eyes or if ingested, seek immediate medical attention.
3. Sodium Azide reacts with lead and copper plumbing, 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. Tietz NW Clinical Guide to Laboratory Tests. Philadelphia, Pa: WB Sanders, 1995: 442 - 444.
2. Marcovina, S.M., Albers, J.J., Wijsman, E., Zhang, Z., Chapman, N.H. and Kennedy, H. (1996). Differences in Lp (a) concentrations and apo (a) polymorphs between black and white Americans. Journal of Lipid Research 37: 2569 – 2585
3. Lothar Thomas. Clinical Laboratory Diagnostics. 1st Edition. TH Books.
4. Kronenberg, Lobentanz, Konig, Utermann and Dieplinger; (1994), Journal of Lipid Research 35:1318-1328.
5. Marcovina, S.M., Albers, J.J., Scanu, A.M. et al. (2000) Use of a Reference Material Proposed by the International Federation of Clinical Chemistry and Laboratory Medicine to Evaluate Analytical Methods for the Determination of Plasma Lipoprotein (a). Clinical Chemistry 46: (12) 1956 - 1967
6. Jenner, J.L., Ordovas, J.m., Lamon-Fava, S. et al. (1993). Effects of Age, Sex and Menopausal Status on Plasma Lipoprotein (a) Levels. The Framingham Offspring Study. Circulation 87: 1135 – 1141.

INDEX OF SYMBOLS

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

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