Pariksha Biotech
A game changer in IVD

APO A1 Estimation Kit

High-Q Apolipoprotein A-I

Turbidimetric Immuno Assay (TIA)

HIGH®
Command on Quality

Intended Use:
Kit for the quantitative determination of Apolipoprotein A1 in human Serum and Plasma.

Principle:
Turbidimetric test for the measurement of apolipoprotein A-I in human serum or plasma. Anti- Apo A-I antibodies when mixed with samples containing Apo A-I , form insoluble complexes. These complexes cause an absorbance change, dependent upon the Apo A-I concentration of the patient sample, that can be quantified by comparison from a calibrator of known Apo A-I concentration

Clinical Significance:
Apo A-I is the major structural apolipoprotein in HDL and constitutes about 70% of the total protein. Apo A-I is a cofactor for lecithin-cholesterol-acyl- transferase (LCAT), the enzyme responsible for forming cholesteryl esters in plasma and plays and important role in the transport of cholesterol from peripheral tissues to the liver, to be finally excreted. Measurements of Apo A-I concentration is specially important in detecting coronary heart disease risk (CHD) as well as in the diagnostic of hyperlipoproteinemia. Concentrations < 120 mg/L are associated to an increased CHD risk, while concentrations ≥ 160 mg/L may even protect from the same risk. Patients with deficiencies in Apo A-I synthesis may highly increase the CHD risk.

Tanger disease, a consequence of an Apo A-I catabolism defect, is characterized by several reduced plasma HDL cholesterol (HDL-c) concentration, abnormal HDL composition and accumulation of cholesteryl esters in many body tissues. Plasma HDL-c and Apo A-I concentrations in homozygotes are very low, while Apo A-II concentration is less than 10% of its normal concentration. Heterozygotes are characterized by half-normal concentration of HDL-c, Apo AI and Apo –II. Current evidence suggests that these patients have increased incidence of CHD.

Reagents

Diluent (R1): Tris buffer 20 mmol/L, PEG, pH 8.3. Sodium azide 0.95 g/L.

Antibody (R2) : Goat Serum, Anti Human APO A1, Tris buffer 50 mmol/L. Sodium azide 0.95 g/L.

APO A1 Calibrator: Calibrator is available as Lyophilized Calibrator.. **Reconstitute Calibrator with 1.0 ml of Distilled Water and keep it for 30 Minutes.** Mix gently and make a uniform suspension. Reconstituted Calibrator is stable for 60 Days once stored properly at 2-8°C. Aliquot it in to small volumes and store at 2-8°C for the contamination free use and for good reconstitution stability. Calibrator is stable for 6 Months when frozen at -20°C if the repeated freeze and thaw cycles are avoided. Calibrator needs to be serially diluted as per the procedure mentioned in the Calibrator insert.

Calibrator Traceability

The Assay and the values of the Calibrator Concentration have been standardized against the certified reference Materials WHO/IFCC SP1-01 (CDC,USA) .

Reagent Preparation:
Reagents are ready to use.

Specimen:

Fresh serum or Plasma. EDTA or Heparin should be used as anti coagulant. Stable 15 days at 2-8ºC or 3 months at –20ºC.

Samples with presence of fibrin should be centrifuged before testing.

Do not use highly hemolized or lipemic samples.

Test Procedure: System Parameters:

Calibration Method	**Endpoint-Bichromatic-Non Linear-Multical-Spline**
Reaction Direction	Increasing
Primary Wave Length	340
Secondary Wave Length	700 (600-700)
Flow Cell Temp.	37°C
Blank	Reagent Blank
Reagent Volume	400 µl (R1) + 100 µl (R2)
Sample Volume)	5 µl
Calibrators Conc: 1,2,3,4,5	Lot Specific (Check the labels))
Units	mg/dL
Low normal	110
High normal	170
Linearity	250

Procedure

Reagent	Reagent Blank	C	S
R1	400 µL	400 µL	400 µL
Calibrators (1,2,3,4,5)	----	5 µL	----
Sample	----	----	5 µL
Incubate 5 Minutes at 37°C			
R2	100 µL	100 µL	100 µL

Mix carefully and wait for about 5 minutes. Measure the absorbance of calibrators and of the samples against reagent blank.

Calculations:
The Multipoint Non Linear /Semi logarithmic calibration model was used , and the Spline function was used as the calculation model. The dose / response curve was made based on the value of the calibrator and the change of absorbance. The concentration of Prealbumin in the sample could be calculated on the dose/ response curve based on the change of absorbances

Quality Control:

Control Sera are recommended to monitor the performance of manual and automated assay procedures.

Each laboratory should establish its own Quality Control scheme.

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Reference Range
Mean values"
Men : Desirable > 110 mg/dL
Women Desirable > 120 mg/dL

Each laboratory should check if the reference ranges aretransferable to its own patient population and determine ownreference ranges if necessary.

Clinical Interpretation

Risk of CHD:

Several studies indicate that the Apo-B / Apo-A1 Ratio perfectly reflects the CHD

Men: Lower Risk: <0.7
Average Risk: 0.7-0.9
Higher Risk: >0.9

Women: Lower Risk: <0.6
Average Risk: 0.6-0.8
Higher Risk: >0.8

(Apo-A alone and APO-B alone can not predict the CHD properly. Together when Apo-A1 and Apo- B are estimated as a ratio they are the better risk indicators of CHD. In order to estimate APO-B/APO-A1 Ratio one has to estimate APO A1 and Apo-B too. Pariksha offers both APO-A1 and Apo-B Test kits

Precision: The reagent has been tested for 20 days, using three levels of serum in a EP5-based study (NCCLS).

	Ep5		CV (%)	
	27.22 mg/dL	65.74 mg/dL	131.07 mg/dL	
Total	4 %	3.7 %	4.8 %	
Within Run	2.2 %	0.8 %	1.1 %	
Between Run	2.3 %	1.3 %	1.4 %	
Between Day	2.4 %	3.3 %	4.5 %	

Accuracy: Results obtained using this reagent (y) were compared to those obtained with a Bayer immunoturbidimetric method. 39 samples ranging from 50 to 200 mg/dL of Apo A-I were assayed. The correlation coefficient (r) was 0.92 and the regression equation y = 1.18 x - 37.8.

Interferences:
Hemoglobin (20 g/L), bilirrubin (40 mg/dL), lipemia (< 5 g/L), and rheumatoid factor (800 IU/mL) do not interfere. Other substances may interfere.

Notes:
Clinical diagnosis should not be made on findings of a single test result, but should integrate both clinical and laboratory data.

eIFU Indicator

Pariksha's world inside
SCAN TO EXPLORE MORE

Manufactured in India by :
Pariksha Biotech Pvt Ltd,
Plot no.1/B-14, SVICE,
Balanagar,
Hyderabad-500037
Telangana State

Bibliography:
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Ordering Information

Ref./Cat. No.	Pack Size	Presentation
P-APOA1 - 25	25 ml	Two Liquid Reagents with Calibrator

Product Features

- **Quantitative Turbidimetric Immuno Assay (TIA)**
- **Two liquid reagents (Diluent and Antibody).**
- **Lyophilized Calibrator Provided**
- **5 Minutes Endpoint Bichromatic Spline Assay**
- **Linearity : 250 mg/dL**
- **Available as multipurpose reagents and dedicated system packs**

Symbols used with IVD devices

	Date of manufacture		Manufactured by
IVD	In vitro diagnostic device		Keep away from sunlight
	Do not freeze		This way up
	Use by (yyyy-mm-dd or mm/yyyy)	R	Reagent
CAL	Calibrator Material	LOT	Batch code
2°C 8°C	Temperature limitation (store at)	CONTROL	Control
	Consult instructions for use		Keep dry Keep away from rain
REF	Catalog Number		

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