Pariksha Biotech
A game changer in IVD

APO B Estimation Kit

High-Q Apolipoprotein B

Turbidimetric Immuno Assay (TIA)

HIGH®
Command on Quality

Intended Use: Kit for the quantitative determination of polipoprotein B in human Serum and Plasma.

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

Clinical Significance:
APO B is the major structural apolipoprotein in VLDL (Very Low Density Lipids), LDL (Low Density Lipids) lipoproteins and chylomicron. The most important function is the transport of rich tryglicerides lipoproteins from liver and intestine to other tissues. Apo B exists in two forms: APO B-100 and APO B-48. APO B-100, the most important component of LDL, is synthesized in the liver and excreted in plasma as part of VLDL. APO B-48, the most important component of chylomicrons, is synthesized in the intestine.
Several studies demonstrated that in people with coronary heart disease (CHD), changes in the serum concentrations of APO A-I and APO B are similar to those for HDL and LDL, respectively and whereas, are somewhat better discriminators of people with CHD than the LDL and HDL cholesterol concentrations.
The hiperbetalipoproteinemia is characterized by increased LDL APO B-100 concentrations with normal or moderately increased concentrations of LDL cholesterol. The ratio of LDL cholesterol to APO B-100 is therefore reduced in these patients.
Defects in the APO B structure or lipoproteins containing APO B prevent the secretion of triglycerides rich intestinal and hepatic lipoproteins; this disorder occurs in abetaliporpteinemia or homozygous hypobetalipoproteinemia.

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 B, Tris buffer 50 mmol/L. Sodium azide 0.95 g/L.

APO B 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)	10 µl
Calibrators Conc: 1,2,3,4,5	Lot Specific (Check the labels))
Units	mg/dL
Linearity	250

Procedure

Reagent	Reagent Blank	C	S
R1	400 µL	400 µL	400 µL
Calibrators (1,2,3,4,5)	----	10 µL	----
Sample	----	----	10 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 Apo-B 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.

Performance Charesterestics:

Linearity: Up to 250 mg/dL, under the described assay conditions. Samples with higher concentrations, should be diluted 1/5 in NaCl 9 g/L and retested again. The linearity limit depends on the sample / reagent ratio. It will be higher by decreasing the sample volume, although the sensitivity of the test will be proportionally decreased.

Detection Limit: Values less than 3.02 mg/dL give non-reproducible results.

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Reference Range- Apo-B
Mean values"
Men : Desirable < 150 mg/dL
Women Desirable < 155 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 (%)		
	23.92 mg/dL	59.08 mg/dL	119.07 mg/dL
Total	7.4 %	4.3 %	3.6%
Within Run	2.0 %	1.4 %	1.0 %
Between Run	3.7 %	2.2 %	1.8 %
Between Day	6.1 %	3.4 %	3.0 %

Accuracy: Results obtained using this reagent (y) were compared to those obtained with a similar immunoturbidimetric method. 48 samples ranging from 50 to 200 mg/dL of APO B were assayed. The correlation coefficient (r) was 0.982 and the regression equation y = 0.996x + 5.112

Interferences:
Hemoglobin (20 g/L), bilirrubin (40 mg/dL), lipemia (2.5 g/L), and rheumatoid factor (800 UI/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.

Bibliography:

1. Clinical Guide to Laboratory Tests, Edited by NW Tietz W B Saunders Co ., Phipladelphia, 483, 1983.
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4. Freedman DS et al. N Eng J Med 1986; 315: 721-726.
5. Sakurabayashi I et al. Clinica Chimica Acta 2001; 312: 87-95.
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Ordering Information

Ref./Cat. No.	Pack Size	Presentation
P-APOB- 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

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		

eIFU Indicator

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