Apolipoprotein B FS*

Order Information

Cat. No.	Kit size				
1 7112 99 10 021	R1	5 x 25 mL	+	R2	1 x 25 mL
1 7112 99 10 930	R1	4 x 20 mL	+	R2	2 x 8 mL
1 7112 99 10 935	R1	2 x 20 mL	+	R2	1 x 8 mL

Intended Use

Diagnostic reagent for quantitative in vitro determination of apolipoprotein B (Apo B) in serum or plasma on photometric systems.

Summary

Apolipoprotein B (Apo B) is the principal protein component of low density lipoprotein (LDL) which transports cholesterol to the cells thus contributing to atherosclerotic plaque formation in the arteries. Elevated Apo B levels are strongly associated with coronary heart disease (CHD) because of the close relation between Apo B and degree of atherosclerosis. While determination of total cholesterol and triglycerides is used for screening of coronary risk, measurement of Apo B beside apolipoprotein A1 and lipoprotein (a) provides useful information concerning various disorders of the lipoprotein metabolism and can be an alternative to the determination of LDL-cholesterol. Apo B measurements are as well very useful for monitoring of the lipid-lowering therapy. [1,2]

Method

Immunoturbidimetric test

Determination of Apo B concentration by photometric measurement of antigen antibody reaction of antibodies to Apo B with Apo B present in the sample.

Reagents

Components and Concentrations

R1:	TRIS	pH 7.5	100 mmol/L
R2:	TRIS	pH 7.5	65 mmol/L
	Anti-human apolipoprotein B antibody (goat)		< 1%

Storage and Stability

Reagents are stable up to the date of expiry indicated on the kit, if stored at 2 – 8°C and contamination is avoided. Do not freeze the reagents and protect them from light.

Warnings and Precautions

1. The reagents contain sodium azide (0.95 g/L) as preservative. Do not swallow! Avoid contact with skin and mucous membranes.
2. Reagent 2 contains animal material. Handle the product as potentially infectious according to universal precautions and good clinical laboratory practices.
3. In very rare cases, samples of patients with gammopathy might give falsified results [3].
4. Please refer to the safety data sheets and take the necessary precautions for the use of laboratory reagents. For diagnostic purposes, the results should always be assessed with the patient's medical history, clinical examinations and other findings.
5. For professional use only.

Waste Management

Refer to local legal requirements.

Reagent Preparation

The reagents are ready to use.

Materials Required

General laboratory equipment

Specimen

Serum or heparin plasma

Stability [4]:

1 day	at	20 – 25°C
3 days	at	4 – 8°C
2 months	at	–20°C

Only freeze once. Discard contaminated specimens.

Assay Procedure

Applications for automated systems are available on request.

Wavelength	Hg 340 nm
Optical path	1 cm
Temperature	37°C
Measurement	Against reagent blank

	Blank	**Sample/Calibrator**
Sample/Calibrator	-	2.5 µL
Dist. Water	2.5 µL	-
Reagent 1	250 µL	250 µL
Mix, incubate for 3 – 5 min., read absorbance (A1), then add:		
Reagent 2	50 µL	50 µL
Mix, incubate for 5 min., read absorbance (A2).		

ΔA = (A2 – A1) Sample or calibrator

Calculation

The concentration of apolipoprotein B in unknown samples is derived from a calibration curve using an appropriate mathematical model such as logit/log. The calibration curve is obtained with 5 calibrators at different levels and distilled water or aqueous NaCl solution (9 g/L) for determination of the zero value.

Stability of calibration: 4 weeks

Calibrators and Controls

DiaSys TruCal Apo A1/B calibrator is recommended for calibration. TruCal Apo A1/B calibrator values have been made traceable to a commercially available measurement procedure, standardized against IFCC reference standards (WHO-IRP October 1992) SP3-07. Use DiaSys TruLab L for internal quality control. Each laboratory should establish corrective action in case of deviations in control recovery.

	Cat. No.	Kit size
TruCal Apo A1/B	1 7170 99 10 045	3 x 2 mL
TruLab L Level 1	5 9020 99 10 065	3 x 3 mL
TruLab L Level 2	5 9030 99 10 065	3 x 3 mL

Performance Characteristics

Data evaluated on BioMajesty® JCA-BM6010/C

Exemplary data mentioned below may slightly differ in case of deviating measurement conditions.

Measuring range up to 250 mg/dL, depending on the concentration of the highest calibrator. When values exceed this range, samples should be diluted 1 + 1 with NaCl solution (9 g/L) and the result multiplied by 2.	
Limit of detection**	0.5 mg/dL
No prozone effect up to 1000 mg/dL.	

Interfering substance	**Interferences ≤ 10% up to**
Ascorbic acid	30 mg/dL
Bilirubin (conjugated and unconjugated)	60 mg/dL
Hemoglobin	400 mg/dL
Lipemia (triglycerides)	2000 mg/dL
For further information on interfering substances refer to Young DS. [5,6]	

Precision			
Within run (n=20)	**Sample 1**	**Sample 2**	**Sample 3**
Mean [mg/dL]	60.7	80.8	98.6
CV [%]	1.36	1.27	1.23
Between day (n=20)	**Sample 1**	**Sample 2**	**Sample 3**
Mean [mg/dL]	67.7	141	201
CV [%]	0.923	1.31	1.55

Method comparison (n=100)	
Test x	Competitor Apolipoprotein B
Test y	DiaSys Apolipoprotein B FS
Slope	0.992
Intercept	–15.3 mg/dL
Coefficient of correlation	0.999

** lowest measurable concentration which can be distinguished from zero; mean + 3 SD (n = 20) of an analyte free specimen.

Conversion Factor
Apo B [mg/dL] x 0.0182 = Apo B [µmol/L]

Reference Range

Mean values according to data reported in [7]

Women	75 – 150 mg/dL	1.37 – 2.73 µmol/L
Men	80 – 155 mg/dL	1.46 – 2.82 µmol/L

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

Clinical Interpretation

Several studies indicate that increased concentrations of Apo B (> 150 mg/dL in women and > 155 mg/dL in men) and decreased concentrations of Apo A1 (< 120 mg/dL in women and < 110 mg/dL in men) may be good predictors of risk of CHD [2].

Literature

1. Bhatnagar D, Durrington PN. Measurement and clinical significance of apolipoproteins A-I and B. In: Rifai N, Warnick GR, Dominiczak MH, eds. Handbook of lipoprotein testing. Washington: AACC Press, 1997: p. 177-98.
2. Rifai N, Bachorik PS, Albers JJ. Lipids, lipoproteins and apolipoproteins. In: Burtis CA, Ashwood ER, editors. Tietz Textbook of Clinical Chemistry. 3rd ed. Philadelphia: W.B Saunders Company; 1999. p. 809-61.
3. Bakker AJ, Mücke M. Gammopathy interference in clinical chemistry assays: mechanisms, detection and prevention. ClinChemLabMed 2007;45(9):1240-1243.
4. Guder WG, Zawta B et al. The Quality of Diagnostic Samples. 1st ed. Darmstadt: GIT Verlag; 2001; p. 18-9.
5. Young DS. Effects of Drugs on Clinical Laboratory Tests. 5th ed. Volume 1 and 2. Washington, DC: The American Association for Clinical Chemistry Press 2000.
6. Young DS. Effects on Clinical Laboratory Tests - Drugs Disease, Herbs & Natural Products, https://clinfx.wiley.com/aaccweb/aacc/, accessed on December 2020. Published by AACC Press and John Wiley and Sons, Inc.
7. Jungner I, Marcovina SM, Walldius G, Holme I, Kolar W, Steiner E. Apolipoprotein B and A-I values in 147576 Swedish males and females, standardized according to the World Health Organization-International Federation of Clinical Chemistry First International Reference Materials. Clin Chem 1998; 44: 1641-9.

IVD CE

DiaSys Diagnostic Systems GmbH
Alte Strasse 9 65558 Holzheim Germany
www.diasys-diagnostics.com

* Fluid Stable