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

Kits for use in conjunction with DiaSys CE applications.

Intended Use

Diagnostic reagent for quantitative in vitro determination of apolipoprotein B in human serum or heparin plasma on automated 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 and protect from light.

The open-vial stability of the reagent is 18 months until expiry date.

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 material of biological origin. Handle the product as potentially infectious according to universal precautions and good clinical laboratory practice.
3. In very rare cases, samples of patients with gammopathy might give falsified results [3].
4. In case of product malfunction or altered appearance that could affect the performance, contact the manufacturer.
5. Any serious incident related to the product must be reported to the manufacturer and the competent authority of the Member State where the user and/or patient is located.
6. Please refer to the safety data sheets (SDS) 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.
7. For professional use only.

Waste Management

Refer to local legal requirements for chemical disposal regulations as stated in the relevant SDS to determine the safe disposal.

Warning: Handle waste as potentially biohazardous material. Dispose of waste according to accepted laboratory instructions and procedures.

Reagent Preparation

The reagents are ready to use.

Materials Required

General laboratory equipment

Specimen

Human serum or heparin plasma

Only use suitable tubes or collection containers for specimen collection and preparation.

When using primary tubes, follow the manufacturer's instructions.

Stability [4]:

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

Only freeze once. Discard contaminated specimens.

Assay Procedure

Basic settings for BioMajesty® JCA-BM6010/C

Wavelength	340/694 nm
Temperature	37°C
Measurement	Endpoint
Sample/Calibrator	1.0 µL
Reagent 1	100 µL
Reagent 2	20 µL
Addition reagent 2	Cycle 19 (286 s)
Absorbance 1	Cycle 17/18 (231 s/244 s)
Absorbance 2	Cycle 41/42 (586 s/600 s)
Calibration	Logit Log 3

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.

Conversion Factor

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

Calibrators and Controls

DiaSys TruCal Apo A1/B calibrator is recommended for calibration. 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 Level 1 and Level 2 for internal quality control. All target values of the controls are traceable to DiaSys reagent/calibrator system. Quality control must be performed after calibration. Control intervals and limits have to be adapted to the individual requirements of each laboratory. Results must be within the defined ranges. Follow the relevant legal requirements and guidelines. 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

Measuring range up to 250 mg/dL, depending on the concentration of the highest calibrator. Linearity is given within ± 5%. 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.	

Interference by	Interferences ≤ 10% up to	Analyte concentration [mg/dL]
Ascorbic acid	30 mg/dL	104
Bilirubin (conjugated)	60 mg/dL	105
Bilirubin (unconjugated)	60 mg/dL	104
Hemolysis	400 mg/dL	103
Lipemia (triglycerides)	2000 mg/dL	102
For further information on interfering substances, refer to the literature [5-7].		

Precision			
Repeatability (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 (BioMajesty® JCA-BM6010/C)
Test y	DiaSys Apolipoprotein B FS (BioMajesty® JCA-BM6010/C)
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.

Reference Range [8]

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.
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IVD CE

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* Fluid Stable