Apolipoprotein A1 FS*

Order Information

Cat. No.	Kit size				
1 7102 99 10 021	R1	5 x 25 mL	+	R2	1 x 25 mL
1 7102 99 10 930	R1	4 x 20 mL	+	R2	2 x 8 mL
1 7102 99 10 935	R1	2 x 20 mL	+	R2	1 x 8 mL

Intended Use

Diagnostic reagent for quantitative in vitro determination of apolipoprotein A1 (Apo A1) in serum or plasma on photometric systems.

Summary

Apolipoprotein A1 (Apo A1) is the principal protein component of high density lipoprotein (HDL) which removes cholesterol from the cells and thus has a protective effect to atherosclerosis. Epidemiological studies have shown an inverse relationship between levels of HDL respectively Apo A1 and prevalence of coronary heart disease (CHD). While determination of total cholesterol and triglycerides is used for screening of coronary risk, measurement of Apo A1 beside lipoprotein (a) and apolipoprotein B provides further useful information in lipid disorders and can be an alternative to the measurement of HDL cholesterol. [1,2]

Method

Immunoturbidimetric test

Determination of Apo A1 concentration by photometric measurement of antigen antibody reaction between antibodies to human Apo A1 and Apo A1 present in the sample.

Reagents

Components and Concentrations

R1:	TRIS	pH 7.5	100 mmol/L
R2:	TRIS	pH 7.5	100 mmol/L
	Anti-human apolipoprotein A1 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 580 nm (500 – 700 nm)
Optical path	1 cm
Temperature	37°C
Measurement	Against reagent blank

	Blank	**Sample/Calibrator**
Sample/Calibrator	-	2 µL
Dist. Water	2 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).		

$\Delta A = (A2 - A1)$ Sample or calibrator

Calculation

The concentration of apolipoprotein A1 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.

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). For standardization of Apo A1 the reference standard SP1-01 was used. 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 500 mg/dL.	

Interfering substance	**Interferences ≤ 10% up to**
Ascorbic acid	30 mg/dL
Bilirubin (conjugated and unconjugated)	60 mg/dL
Hemoglobin	500 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]	107	133	165
CV [%]	1.18	1.20	1.50
Between day (n=20)	**Sample 1**	**Sample 2**	**Sample 3**
Mean [mg/dL]	130	286	468
CV [%]	2.13	1.51	2.04

Method comparison (n=94)	
Test x	Competitor Apolipoprotein A1
Test y	DiaSys Apolipoprotein A1 FS
Slope	0.967
Intercept	–3.11 mg/dL
Coefficient of correlation	0.996

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

Conversion Factor
Apo A1 [mg/dL] x 0.357 = Apo A1 [µmol/L]

Reference Range

Mean values according to data reported in [7]

Women	120 – 190 mg/dL	42.8 – 67.8 µmol/L
Men	110 – 170 mg/dL	39.3 – 60.7 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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4. Guder WG, Zawta B et al. The Quality of Diagnostic Samples. 1st ed. Darmstadt: GIT Verlag; 2001; p. 18-9.
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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.

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* Fluid Stable