BioMajesty®

Apolipoprotein A1 FS*

Order Information

Cat. No.	Kit size
1 7102 99 10 966	Σ 200 (R1: 2 x 100, R2: 2 x 100)

Intended Use

Diagnostic reagent for quantitative in vitro determination of apolipoprotein A1 (Apo A1) in serum or plasma on BioMajesty® JCA-BM6010/C.

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. The bottles are placed directly into the reagent rotor.

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.

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

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. In case of higher concentrations re-measure samples after manual dilution with NaCl solution (9 g/L) or use rerun function.	
Limit of detection**	0.5 mg/dL
No prozone effect up to 500 mg/dL.	
Onboard stability	6 weeks
Calibration stability	6 weeks

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]

BioMajesty®

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.
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

BioMajesty

Apolipoprotein A1 FS

Chemistry code 10 710

Application for serum and plasma samples

This application was set up and evaluated by DiaSys. It is based on the standard equipment at that time and does not apply to any equipment modifications undertaken by unqualified personnel.

Analytical Conditions	
R1 volume	100
R2e volume	0
R2 volume	20
R1 diluent vol	0
R2e diluent vol	0
R2 diluent vol	0
Sample vol (S)	1.0
Sample vol (U)	1.0
Reagent 1 mix	weak
Reagent 2e mix	weak
Reagent 2 mix	weak
Reaction time	10

Endpoint Method	
Re.absorb (u)	9.999
Re.absorb (d)	-9.999

Calculation Method Setting	
M-DET.P.I	0
M-DET.P.m	41
M-DET.P.n	42
S-DET.P.p	17
S-DET.P.r	18
Check D.P.I.	0
Limit value	0.003
Variance	10
Reac.type	Inc

Sub-analy. Conditions	
Name	APOA1
Digits	2
M-wave L.	571
S-wave.L	694
Analy.mthd.	EPA
Calc.mthd.	MSTD
Qualit. judge	No

Reaction Rate Method	
Cycle	2
Factor	2
E2 corre	Not do
Blank (u)	9.999
Blank (d)	-9.999
Sample (u)	9.999
Sample (d)	-9.999

Analysis Test Condition Setting (M)		
Sample Type	**Serum**	**Urine**
Reac. sample vol.	1.0	1.0
Diluent method	No dil	No dil
Undil. sample vol.	0	0
Diluent volume	0	0
Diluent position	0	0

Prozone	
Prozone form	No
Prozone limit	9.999
Prozone judge	Upper limit
Judge limit	9.999
M-DET.P.m	0
M-DET.P.n	0
S-DET.P.p	0
S-DET.P.r	0

MULTI-STD Setting			
Formula	Logit Log 3	**Axis Conv**	No conv
Blank	Blank is 0	**Points**	6

	FV	Reac. smp. vol.	Dil. method	Dil. smp. vol.	Diluent vol.	Diluent pos.	STD H	STD L
BLK	#	1.0	No dil	0	0	0	9.999	-9.999
1	#	1.0	With dil	10	40	0	9.999	-9.999
2	#	1.0	With dil	20	30	0	9.999	-9.999
3	#	1.5	With dil	20	30	0	9.999	-9.999
4	#	2.0	With dil	20	30	0	9.999	-9.999
5	#	1.0	No dil	0	0	0	9.999	-9.999

entered by user