

Apolipoprotein B FS*

Order Information

Cat. No.	Kit size
1 7112 99 10 921	 400 (4 x 100)

Intended Use

Diagnostic reagent for quantitative in vitro determination of apolipoprotein B (Apo B) in serum or plasma on DiaSys respons[®]910.

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

Immunturbidimetric 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		< 1% (goat)

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

- The reagents contain sodium azide (0.95 g/L) as preservative. Do not swallow! Avoid contact with skin and mucous membranes.
- Reagent 2 contains animal material. Handle the product as potentially infectious according to universal precautions and good clinical laboratory practices.
- In very rare cases, samples of patients with gammopathy might give falsified results [3].
- 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.
- 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) 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

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

Measuring range up to 240 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**	1.0 mg/dL	
No prozone effect up to 1200 mg/dL.		
Onboard stability	14 days	
Calibration stability	7 days	
Interfering substance	Interferences ≤ 10% up to	Analyte concentration [mg/dL]
Ascorbic acid	25 mg/dL	90.0
Hemoglobin	600 mg/dL	82.5
	600 mg/dL	110
Bilirubin (conjugated)	40 mg/dL	67.1
	50 mg/dL	104
Bilirubin (unconjugated)	30 mg/dL	69.4
	50 mg/dL	111
Lipemia (triglycerides)	2000 mg/dL	52.8
	2000 mg/dL	98.0
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]	32.2	79.4	134
CV [%]	2.08	1.66	1.47
Between day (n=20)	Sample 1	Sample 2	Sample 3
Mean [mg/dL]	36.3	67.5	150
CV [%]	2.86	4.96	4.40

Method comparison (n=97)	
Test x	DiaSys Apolipoprotein B FS (Hitachi 917)
Test y	DiaSys Apolipoprotein B FS (respons [®] 910)
Slope	1.004
Intercept	-2.58 mg/dL
Coefficient of correlation	0.994

** according to CLSI document EP17-A, Vol. 24, No. 34

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.



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* Fluid Stable

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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.

Identification	
This method is usable for analysis:	Yes
Twin reaction:	No
Name:	APOB
Shortcut:	
Reagent barcode reference:	703
Host reference:	

Technic	
Type:	End point
First reagent:[μ L]	200
Blank reagent	Yes
Sensitive to light	
Second reagent:[μ L]	40
Blank reagent	Yes
Sensitive to light	
Main wavelength:[nm]	340
Secondary wavelength:[nm]	700
Polychromatic factor:	1.000
1 st reading time [min:sec]	(04:24)
Last reading time [min:sec]	10:00
Reaction way:	Increasing
Linear Kinetics	
Substrate depletion: Absorbance li	
Linearity: Maximum deviation [%]	
Fixed Time Kinetics	
Substrate depletion: Absorbance limit	
Endpoint	
Stability: Largest remaining slope	
Prozone Limit [%]	

Reagents	
Decimals	
Units	

Sample	
Diluent	DIL A (NaCl)
Hemolysis:	
Agent [μ L]	0 (no hemolysis)
Cleaner	
Sample [μ L]	0
Technical limits	
Concentration technical limits-Lower	1.0
Concentration technical limits-Upper	240
SERUM	
Normal volume [μ L]	3
Normal dilution (factor)	1
Below normal volume [μ L]	9
Below normal dilution (factor)	1
Above normal volume [μ L]	3
Above normal dilution (factor)	6
URIN	
Normal volume [μ L]	3
Normal dilution (factor)	1
Below normal volume [μ L]	9
Below normal dilution (factor)	1
Above normal volume [μ L]	3
Above normal dilution (factor)	6
PLASMA	
Normal volume [μ L]	3
Normal dilution (factor)	1
Below normal volume [μ L]	9
Below normal dilution (factor)	1
Above normal volume [μ L]	3
Above normal dilution (factor)	6
CSF	
Normal volume [μ L]	3
Normal dilution (factor)	1
Below normal volume [μ L]	9
Below normal dilution (factor)	1
Above normal volume [μ L]	3
Above normal dilution (factor)	6
Whole blood	
Normal volume [μ L]	3
Normal dilution (factor)	1
Below normal volume [μ L]	9
Below normal dilution (factor)	1
Above normal volume [μ L]	3
Above normal dilution (factor)	6

Results	
Decimals	2
Units	mg/dL
Correlation factor-Offset	0.000
Correlation factor-Slope	1.000

Range	
Gender	Male
Age	
SERUM	>=80 <=155
URINE	
PLASMA	>=80 <=155
CSF	
Whole blood	
Gender	Female
Age	
SERUM	>=75 <=150
URINE	
PLASMA	>=75 <=150
CSF	
Whole blood	

Contaminants	
Please refer to r910 Carryover Pair Table	

Calibrators details		
Calibrator list	Concentration	
Cal. 1/Blank	0	
Cal. 2	*	
Cal. 3	*	
Cal. 4	*	
Cal. 5	*	
Cal. 6	*	
	Max delta abs.	
Cal. 1	0.0100	
Cal. 2	0.0100	
Cal. 3	0.0150	
Cal. 4	0.0200	
Cal. 5	0.0200	
Cal. 6	0.0250	
Drift limit [%]	5.0	

Calculations	
Model	Logit (X)
Degree	2

* Enter calibrator value