respons®920

Apolipoprotein B FS*

Order Information

Cat. No.	Kit size
1 7112 99 10 921	Σ 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®920.

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. To avoid carryover interference, please take care of efficient washing especially after use of interfering reagents. Please refer to the DiaSys respons®920 Carryover Pair Table. Carryover pairs and automated washing steps with the recommended cleaning solution can be specified in the system software. Please refer to the user manual.
5. 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.
6. 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 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**	1.5 mg/dL
No prozone effect up to 1000 mg/dL.	
Onboard stability	4 weeks
Calibration stability	4 weeks

Interfering substance	**Interferences ≤ 10% up to**
Ascorbic acid	30 mg/dL
Bilirubin	60 mg/dL
Hemoglobin	1000 mg/dL
Lipemia (triglycerides)	1200 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]	40.1	102	159
CV [%]	2.28	2.76	1.37
Between day (n=20)	**Sample 1**	**Sample 2**	**Sample 3**
Mean [mg/dL]	27.4	99.2	158
CV [%]	4.52	2.96	2.56

Method comparison (n=119)	
Test x	DiaSys Apolipoprotein B FS (Hitachi 917)
Test y	DiaSys Apolipoprotein B FS (respons®920)
Slope	1.087
Intercept	–3.54 mg/dL
Coefficient of correlation	0.991

** 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

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* Fluid Stable

respons®920

Apolipoprotein B FS

Application for serum and plasma

Test Details			Test Volumes			Reference Ranges		
Test	:	APOB				Auto Rerun	☐	
Report Name	:	Apolipoprotein B				Online Calibration	☐	
Unit	:	mg/dL	Decimal Places	:	1	Cuvette Wash	☐	
Wavelength-Primary	:	340	Secondary	:	700	Total Reagents	:	2
Assay Type	:	2-Point	Curve Type	:	Cubic Spline	Reagent R1	:	APOB R1
M1 Start	:	15	M1 End	:	15	Reagent R2	:	APOB R2
M2 Start	:	33	M2 End	:	33	**Consumables/Calibrators:**		
Sample Replicates	:	1	Standard Replicates	:	3	Blank/Level 0		0
Control Replicates	:	1	Control Interval	:	0	Calibrator 1		**
Reaction Direction	:	Increasing	React. Abs. Limit	:	*	Calibrator 2		**
Prozone Limit %	:	97	Prozone Check	:	Lower	Calibrator 3		**
Linearity Limit %	:	0	Delta Abs./Min.	:	0.0000	Calibrator 4		**
Technical Minimum	:	*	Technical Maximum	:	*	Calibrator 5		**
Y = aX + b a=	:	1.0000	b=	:	0.0000			

*Technical limits are automatically defined by the software via the upper and lower calibrator level.
** Enter calibrator value

Test Details			Test Volumes	Reference Ranges
Test	:	APOB		
Sample Type	:	Serum		

Sample Volumes

Normal	:	3.00 µL	Dilution Ratio	:	1	X
Increase	:	6.00 µL	Dilution Ratio	:	1	X
Decrease	:	2.00 µL	Dilution Ratio	:	1	X
Standard Volume	:	3.00 µL				

Reagent Volumes and Stirrer Speed

RGT-1 Volume	:	200 µL	R1 Stirrer Speed	:	High
RGT-2 Volume	:	40 µL	R2 Stirrer Speed	:	High

Sample Types

- ☑ Serum
- ☐ Urine
- ☐ CSF
- ☑ Plasma
- ☐ Whole Blood
- ☐ Other

Test Details			Test Volumes	Reference Ranges
Test	:	APOB		
Sample Type	:	Serum		
Reference Range	:	DEFAULT		
Category	:	Male		

Reference Range

		Lower Limit (mg/dL)	Upper Limit (mg/dL)
Normal	:	80.00	155.00
Panic	:	0.00	0.00

Sample Types

- ☑ Serum
- ☐ Urine
- ☐ CSF
- ☑ Plasma
- ☐ Whole Blood
- ☐ Other