respons®920

Apolipoprotein A1 FS*

Order Information

Cat. No.	Kit size
1 7102 99 10 921	Σ 400 (4 x 100)

Intended Use

Diagnostic reagent for quantitative in vitro determination of apolipoprotein A1 (Apo A1) in serum or plasma on DiaSys respons®920.

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. 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). 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**	0.8 mg/dL
No prozone effect up to 500 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)	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]	49.4	87.0	137
CV [%]	1.83	1.75	1.83
Between day (n=20)	**Sample 1**	**Sample 2**	**Sample 3**
Mean [mg/dL]	50.1	116	200
CV [%]	3.22	1.42	1.51

Method comparison (n=126)	
Test x	DiaSys Apolipoprotein A1 FS (Hitachi 917)
Test y	DiaSys Apolipoprotein A1 FS (respons®920)
Slope	1.022
Intercept	0.824 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.
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 A1 FS

Application for serum and plasma

Test Details			Test Volumes			Reference Ranges		
Test	:	APOA1				Auto Rerun	☐	
Report Name	:	Apolipoprotein A1				Online Calibration	☐	
Unit	:	mg/dL	Decimal Places	:	2	Cuvette Wash	☐	
Wavelength-Primary	:	578	Secondary	:	660	Total Reagents	:	2
Assay Type	:	2-Point	Curve Type	:	Polynomial	Reagent R1	:	APOA1 R1
M1 Start	:	15	M1 End	:	15	Reagent R2	:	APOA1 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	:	APOA1		
Sample Type	:	Serum		

Sample Volumes

Normal	:	2.00 µL	Dilution Ratio	:	1	X
Increase	:	6.00 µL	Dilution Ratio	:	1	X
Decrease	:	2.00 µL	Dilution Ratio	:	2	X
Standard Volume	:	2.00 µL				

Reagent Volumes and Stirrer Speed

RGT-1 Volume	:	200 µL	R1 Stirrer Speed	:	Medium
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	:	APOA1		
Sample Type	:	Serum		
Reference Range	:	DEFAULT		
Category	:	Male		

Reference Range

		Lower Limit (mg/dL)	Upper Limit (mg/dL)
Normal	:	110.00	170.00
Panic	:	0.00	0.00

Sample Types

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