
 CUSTOMISED SOLUTIONS FOR YOUR LABORATORY	EN	<b>Apolipoprotein B</b>			<b>Instruction For Use</b>		 <b>IVD</b>	Rev.E - 15-11-22
		REF	R3330000034	R1: 1x 18.0 mL	R2: 1x 2.4 mL			
		A-R1100000301	R1: 1x 50.0 mL	R2: 1x 6.5 mL				

#### Intended Use

Quantitative determination of Apolipoprotein B in human serum by turbidimetric immunoassay.

**For professional in vitro diagnostic use only.**

#### Diagnostics Implications

Apolipoprotein B is the main protein component of LDL (Low Density Lipoprotein). Apolipoprotein B is necessary for the reaction with LDL receptors in the liver and on cell walls and is thus involved in transporting cholesterol from the liver to the vessel cells. Elevated levels of Apolipoprotein B are frequently found in atherosclerotic vascular changes and are a risk factor for atherosclerosis.

#### Method

Measurement of antigen-antibody reaction by the end-point method.

#### Reagents Provided

The same reagents are supplied in different volume formats depending on the I.S.E. S.r.l. analysers utilised and installed reagent support.

#### Supplied Volumes

	Product Code	
	R3330000034	A-R1100000301
Vial size	18 / 18 mL	50 / 20 mL
Reagent 1	1 x 18.0 mL	1x 50.0 mL
Reagent 2	1x 2.4 mL	1x 6.5 mL

#### Reagent format

Reagent	Format	Code
Reagent 1 – Buffer (liquid)	Ready to Use	116C03
Reagent 2 – Antiserum (liquid)	Ready to Use	116C02

#### Reagent Contents

Reagent 1:	Conc.	U.M.
Phosphate buffered saline	-	-
Enhancer	-	-
Detergent	-	-
Sodium azide	0.95	g/L
Reagent 2:		
Phosphate buffered saline	-	-
Polyclonal goat anti-human Apolipoprotein B	Variable	-
Sodium azide	0.95	g/L

#### Stability and Storage

The reagents are stable until expiry date when kept at 2-8°C. Stability in the instrument is at least 4 weeks if contamination is avoided. Do not freeze.

#### Reagents required but not supplied

- Saline (9 g/L NaCl)
- Calibrators and Controls

Key Reference	Description
R1300001501	APO A1/B Calibrator High, 1 mL
R1400000401	APO A1/B Control, 1 mL

Pooled human serum, liquid and stabilized. Contains 0.95 g/L sodium azide. Values are stated in the insert.

#### Sample collection and storage

Use fresh serum. If the test cannot be carried out on the same day, the serum may be stored at 2 – 8°C for 48 hours. If stored for a longer period, the sample should be frozen.

#### General Assay Procedure

Application sheets are available upon request for use with I.S.E. S.r.l. automated systems. All applications not explicitly approved by I.S.E. S.r.l. cannot be guaranteed in terms of performance and must therefore be established by the operator. Wavelength  $\lambda=340\text{nm}$ .

Sample/Control/Standard: dilute 1:2 in saline 9 g/L. Control/Standard to be reconstituted. Reference curve: generate a reference curve by diluting the standard high level Ref. R1300001501 1:1, 1:2, 1:4, 1:8, 1:16 in saline 9 g/L. Use saline 9 g/L as zero point.

#### Quality control

It is necessary, each time the kit is used, to perform the quality controls and to check that values obtained are within the acceptance range provided in the insert. Each laboratory should establish its own mean and standard deviation and adopt a quality control program to monitor laboratory testing.

*If erratic results occur, please contact an authorised ISE representative.*

#### Normal Ranges

Men: 60 – 138 mg/dL (IFCC)

Women: 52 – 129 mg/dL.

Reference values are considered indicative since each laboratory should establish reference ranges for its own patient population. The analytical results should be evaluated with other information coming from patient's clinical history.

#### Performances

The performance characteristics for the Apolipoprotein B reagents were measured on a clinical chemistry analyzer.

Measuring range:	0 - 330 mg/dL.
Detection Limit:	8 mg/dL
Hookeffect:	No risk
Sensitivity:	0.00049 ABS units/concentration unit

#### Precision of the method

Condition	U.M.	Low	Medium	High
Intra-Run	CV%	5.24	1.16	0.91
Inter-Run	CV%	-	1.02	-

#### Accuracy of the method

Control	U.M.	Assigned	Measured
Aptec	mg/dL	121 (103 - 139)	120
Siemens	mg/dL	97 (82 - 112)	89

Specificity:	Monospecific.
Interferences:	No interference for: Hemoglobin (1000 mg/dL), Bilirubin (20 mg/dL) and Triglyceride (2500 mg/dL).
Limitations:	None
Comparison with nephelometry:	$y = 0.8384x + 24.362$ $r = 0.9886$
Stability at 2 - 8°C:	at least 3 years after production



#### Precautions and Warnings

- In vitro diagnostic use only.
- Refer to the safety data sheets (SDS) and take the necessary precautions for the use of laboratory reagents.
- Do not use after expiry date and do not interchange reagents from different lots.
- Replace caps on reagents immediately after use. Do not switch caps.
- Do not pipet by mouth. Do not smoke, eat, drink or use cosmetics during the use of the reagent. Do not swallow.
- Sodium azide has been reported to form lead or copper azide in laboratory plumbing which may explode on percussion. Flush drains with water thoroughly after disposing of fluids containing sodium azide.
- Polyethyleneglycol is not biohazardous.
- Each donor unit used in the preparation of the reagents, standards and controls was found to be negative for the presence of HIV1 and HIV2 antibodies, as well as for the hepatitis B surface antigen and anti-hepatitis C antibodies, using a method approved by the FDA. However, the material must be considered potentially hazardous and handled with the same care as samples taken from patients.
- Cuts, abrasions, and other skin lesions should be properly protected with an appropriate waterproof dressing.
- Take care to avoid self-inoculation, splashing of mucous membranes or generation of aerosols. Laboratory gloves should be worn while handling patients' samples or disposing of solid or liquid wastes.
- In addition to the eventual risk indications regarding the active components, the reagents contain inactive components such as preservatives (e.g. sodium azide or others) and detergents. The total concentrations of these components are lower than the limits reported by the current directive and following modification and amendments. However, it is recommended to handle reagents carefully, to avoid ingestion and contact with eyes, skin and mucus membranes and to use laboratory reagents according to good laboratory practice.
- All human samples must be handled and disposed of as potentially infectious materials.

#### Disposal of reagent

Disposal of reagents must be performed in accordance with the EC regulations regarding waste, or the local national or regional legislation.











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#### Reporting of serious incidents

The user must report (through the distributor) any serious accident occurring in relation to the device to both the manufacturer and the competent authority of the European Union Member State in which the user and / or patient is established. For other jurisdictions, reports of serious incidents must be produced in accordance with regulatory requirements.

#### Symbols on labels and packaging

	In vitro diagnostic medical device
	Catalog Number
	Lot number
	Manufacturer
	Expiry date
	Temperature limitation
	Consult Instructions for use
	Reagent "n"

#### References

1. Naito, H.K., J. Clin. Immunoassay, 9, 155 (1986)
2. Kottke, B.A., et. al., Mayo Clin. Proc., 61, 313 (1986)
3. Dati, F. et al., Lab. Med. 13, 87 (1989)

Revision history		
Rev.E	15-11-2022	Revision of the document

