

APOLIPOPROTEIN B

Cat. No.	Pack name	Packaging (Content)
BLT20006	APO B	2 x 25 ml APO A1 Buffer 1 x 5 ml APO B Antiserum 1 x 1 ml APO B Calibrator



INTENDED USE

Diagnostic reagent for in vitro quantitative determination of Apolipoprotein B in human serum by turbidimetric immunoassay.

DIAGNOSTIC 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

Buffer

Phosphate buffered saline (pH 7.43).
Polyethylene glycol (60 g/l)
Detergent (0.1%)
Sodium azide (0.09 %).

Antiserum

Phosphate buffered saline (pH 7.43).
Polyclonal goat anti-human Apolipoprotein B (variable).
Sodium azide (0.09 %).

Calibrator

Buffered human plasma, lyophilized and stabilized for 1 ml
Contains 0.09 % sodium azide as preservative.
Concentration : See bottle label

PREPARATION OF REAGENTS

Dissolve the calibrator vial contents in exactly 1 ml distilled water and let stand at + 15 to + 25°C for 30 minutes.
Invert gently to mix. Avoid foam formation and vigorous shaking.

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)

SAMPLE COLLECTION

Use fresh serum. If the test can not 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.

AUTOMATION

Application procedures on clinical chemistry analyzers are available upon request.

MANUAL PROCEDURE

Sample/Control: dilute 1:10 in saline 9 g/l

Reference curve: generate a reference curve by diluting the Apolipoprotein A1/B calibrator 1:10, 1:20, 1:40, 1:80, 1:160 in saline 9 g/l. Use saline 9 g/l as zero point.

Test: Mix 40 µl diluted calibrators, controls and samples with 900 µl buffer. Read optical density (OD1) of samples and calibrators at 340 nm. Add 80 µl antiserum, mix and incubate for 5 minutes at room temperature. Read optical density (OD2) of samples, controls and calibrators at 340 nm.

Calculate ΔOD's, plot a calibrator curve and read the concentration of controls and samples.

REFERENCE VALUES

Men: 60 – 138 mg/dl (IFCC)

Women: 52 – 129 mg/dl

This range is given for orientation only. Each laboratory should establish its own reference values.

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
Hook effect: No risk
Sensitivity: 0.00049 ABS units/concentration unit

Precision:
[%CV]

	Low	Medium	High
Intra-Run	5.24	1.16	0.91
Inter-Run	ND	1.02	ND

Accuracy:
[mg/dl]

Control	Assigned	Measured
ERBA	121 (1.03 - 139)	120
Seronorm	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: $y = 0.8384x + 24.362$
 $r = 0.9886$

PRECAUTIONS AND WARNINGS

- In vitro diagnostic use only.
- 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 calibrators 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.

CONTROL

Control with an appropriate control is recommended.

REFERENCES

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

USED SYMBOLS

LOT Lot Number **IVD** In vitro Diagnostics **i** See Instruction for Use

REF Catalogue Number **M** Manufacturer **CONT** Content

E Expiry Date **T** Storage Temperature

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QUALITY SYSTEM CERTIFIED
ISO 9001 ISO 13485