

# APOLIPOPROTEIN A1

Cat. No.	Pack name	Packaging (Content)
BLT20005	APO A1	2 x 25 ml APO A1 Buffer 1 x 5 ml APO A1 Antiserum 1 x 1 ml APO A1 Calibrator



## INTENDED USE

Diagnostic reagent for in vitro quantitative determination of Apolipoprotein A1 in human serum by turbidimetric immunoassay.

## DIAGNOSTIC IMPLICATIONS

Apo A1 is the main protein component of HDL (High Density Lipoprotein). Apo A1 activates lecithin cholesterol acyltransferase which catalyses the esterification of cholesterol. The resulting esterified cholesterol can then be transported to the liver, metabolised and excreted. Persons with athero-sclerotic vascular changes frequently exhibit decreased levels of Apo A1. Even if the concentrations of apolipoprotein B are normal, a decreased Apo A1 level may be a risk factor for atherosclerotic processes.

Decreased levels of Apo A1 also occur in dyslipoproteinemias, acute hepatic cirrhosis and insulin-treated patients.

## 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 A1 (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 dilution : 1:10 in saline 9 g/l

Reference curve : generate a reference curve by diluting the calibrator high successively 1:10, 1:20, 1:40, 1:80, 1:160 in saline 9 g/l or dilute the calibrator series 1:10 in saline 9 g/l. Use saline 9 g/l as zero point.

Test: Mix 10 µl samples, calibrators and control(s) with 900 µl buffer. Read optical density (OD1) of samples, calibrators and control(s) at 340 nm. Add 80 µl Antiserum. Mix and incubate for 5 minutes at room temperature. Read optical density (OD2) of samples, calibrators and control(s) at 340 nm.

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

## REFERENCE VALUES

Men: 107 - 177 mg/dl (IFCC)

Women: 107 - 205 mg/dl

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

## PERFORMANCES

The performance characteristics for the Apolipoprotein A1 reagents were measured on a clinical chemistry analyzer.

Measuring Range : 0 - 300 mg/dl  
Detection Limit : 4 mg/dl  
Hook Effect : > 5500 mg/dl  
Sensitivity : 0.00074 ABS units/concentration unit

### Precision:

[%CV]

	Low	Medium	High
Intra-Run	3.05	1.12	1.48
Inter-Run	ND	1.63	ND

### Accuracy:

[mg/dl]

Control	Assigned	Measured
ERBA	109 (93 - 125)	108
Seronorm	160 (135 - 183)	169

### Specificity:

Monospecific

**Interferences:** No interference for Hemoglobin (1000 mg/dl), Bilirubin (20 mg/dl) and Triglyceride (2500 mg/dl)

### Limitations:

None

**Comparison with nephelometry:**  $y = 0.9272x + 13.115$   
 $r = 0.9900$

## PRECAUTIONS AND WARNINGS

1. *In vitro* diagnostic use only.

2. 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.

3. Polyethyleneglycol is not biohazardous

4. 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

1. Rifai, N., Ann. Clin. Lab. Science. 18, 429 (1988)
2. Gordon, T. et al., Ann. J. Med. 62, 707 (1977)
3. Rieser, W. et al., Atherosclerosis 37, 157 (1980)
4. Alanpovic, P., Ann. Biol. Clin. 38, 83 (1980)
5. Dati, F. et al., Lab. Med. 13, 87 (1989)

## USED SYMBOLS

 LOT	Lot Number	 IVD	In vitro Diagnostics		See Instruction for Use
 REF	Catalogue Number		Manufacturer	 CONT	Content
	Expiry Date		Storage Temperature		

 Erba Lachema s.r.o., Karásek 2219/1d, 621 00 Brno, CZ  
e-mail: [diagnostics@erbamannheim.com](mailto:diagnostics@erbamannheim.com), [www.erbamannheim.com](http://www.erbamannheim.com)