APO B
Multi-Purpose (MPR)
Liquid Reagent

Glenbio
Diagnostics & Research Laboratory Solutions

KIT SPECIFICATIONS:

Cat. No.	Quantity	Reagent	Storage
GL809AB	1 x 50 ml	APO B - 1	2-8°C
	1 x 10 ml	APO B - 2	
GL819AB	5 x 50 ml	APO B - 1	
	5 x 10 ml	APO B - 2	

INTENDED USE:

In Vitro Diagnostic reagent pack for the quantitative determination of Apolipoprotein B (APO B) in serum and plasma on automated and semi-automated analysers.

SUMMARY AND EXPLANATION:

APO B is the major protein constituent of LDL. APO B levels increase in pregnancy hypercholesterolemia, LDL receptor defects, type II hyperlipidemia and nephrotic syndrome. APO B is measured usually with APO A1. A high level of APO A1 and low level of APO B is related to a low risk of coronary heart disease (CHD).

PRINCIPLE OF THE TEST: [1]

This assay is based on the reaction between antigen and antibody. This reaction forms an insoluble complex producing a turbidity, which is measured spectrophotometrically. The amount of complex formed is directly proportional to the amount of APO B in the sample.

APO B Antigen + Anti-APO B Antibodies ⟶ Antigen/Antibody complex

WARNINGS AND PRECAUTIONS:

For In Vitro Diagnostics Use Only - For Professional Use Only
Carefully read instructions for use. Deviations from this procedure may alter performance of the assay.

Components Colour and Appearance:
Reagent 1: Clear colourless liquid.
Reagent 2: Pale beige liquid.
Any significant changes from the above could indicate that the assay might be compromised. Refer to Laboratory's QC program for actions to be taken. In case of serious damage to the bottle and/or cap, resulting in product leakage and/or contamination, do not use the reagent pack and contact your distributor.

Safety Precautions:
Product is not hazardous under EU specification. Contains Sodium Azide. Material Safety Data Sheet is available upon request.

Handling precautions:
- Take the necessary precautions required for handling all laboratory reagents.
- Do not use components past the expiry date stated on the Bottles.
- Do not Freeze Reagents.
- Do not use components for any purpose other than described in the "Intended Use" section.
- Do not interchange caps among components as contamination may occur and compromise test results.
- Refer to local legal requirements for safe waste disposal.

INSTRUMENTS:

Instruments applications are available upon request.

COMPONENT COMPOSITION:

Component	Ingredients	Concentration in Tests
Reagent 1	TRIS Buffer pH 7.6 with PEG	18.16 mmol/l
	Sodium Chloride	123.20 mmol/l
	DETERGENT & PRESERVATIVES	---
Reagent 2	TRIS Buffer pH 7.6	18.1 6 mmol/l
	Anti APO B antibody	---
	PRESERVATIVES	---

REAGENT PREPARATION AND STABILITY:

Reagent 1 and 2 are ready for use.
Before use, mix reagent by gently inverting each bottle.

If stored and handled properly, components are stable until expiry date stated on the label.

Prepare a range of 6 standards by serially diluting the Glenbio Calibrator (GL9605) in saline as follows:

Dilution	Neat	1/2	1/4	1/8	1/16	1/32
Factor	1	0.5	0.25	0.125	0.063	0.032

TYPE OF SPECIMEN: [2]

Use serum as specimen. Heparin or EDTA plasma can also be used.

It is recommended to follow CLSI procedures (or similar standardised conditions) regarding specimen handling. Specimen should be collected in an appropriate sample container, with proper specimen identification. Plasma/serum should be separated immediately from cells after collection.
Stability[3]*:* up to 3 days at 2-8°C.

TEST PROCEDURE:

Materials required but not supplied:

Description	Catalog. No.	Description	Catalog. No.
APO A1 & B Calibrator	GL9635	Photometer	N/A
Lipid Control Level 1	GL9009	General Laboratory Equipment	N/A
Lipid Control Level 2	GL9019		

Assay procedure:
Wavelength: λ: 340 nm
Temperature: 37°C
Optical path: 1 cm light path.

	Blank	Calibrator	Sample
Reagent 1	1000 µl	1000 µl	1000 µl
Sample	----	----	10 µl
Calibrator	----	10 µl	----
Gently mix and Incubate at 37°C Measure the Optical Density (OD1) after 5 minutes.			
Reagent 2	200 µl	200 µl	200 µl
Gently mix and Incubate at 37°C Measure the Optical Density (OD2) after 10 minutes.			

Calibration:
Using recommended Calibrator, calibrate the assay:
- When using a new reagent kit or changing lot number.
- Following preventive maintenance or replacement of a critical part of the photometer used.
- When Quality Controls are out of range.

Quality Control:
All clinical laboratories should establish an Internal Quality Control program. Verify instrument and reagent performance with recommended controls or similar. The values obtained for QC should fall within manufacturer's acceptable ranges or should be established according to the Laboratory's QC program.
Controls should be assayed:
- Prior reporting patient results.
- Following any maintenance procedure on the photometer used.
- At intervals established by the Laboratory QC programme.

CALCULATION:

- Calculate the ΔAbs of each calibrator and construct a calibration curve. ΔAbs = OD2 – OD1.
- Calculate the ΔAbs for the samples (OD2 – OD1). Determine the corresponding concentration from the calibration curve.

(Conversion Factor: mg/dl x 0.01 = g/l)

EXPECTED VALUES: [2]

Male	mg/dl	g/L	Female	mg/dl	g/L
	63 to 133	0.63 – 1.33		60 to 126	0.60 – 1.26

Each laboratory should establish its own reference range. APO B results should always be reviewed with the patient's medical examination and history.

PERFORMANCE CHARACTERISTICS:

Performance results can vary with the instrument used. Data obtained in each individual laboratory may differ from these values.

Linearity:
This assay is linear across the calibration range.
For samples with a higher concentration, dilute 1:1 with 0.9% NaCl (9g/l) and re-assay. Multiply result by 2.

Prozone:
The system did not show prozone phenomena at least up to 400 mg/dl (4.0 g/L).

Interfering substances:
Results of study are as follows:

Bilirubin (mixed isomers): Less than 10% interference up to 600µmol/l Bilirubin.
Haemolysis: Less than 10% interference up to 5 g/l Haemoglobin.
Lipemia: Less than 10% interference up to 5 g/l Intralipid.

Sensitivity:
The Lowest Detectable Level was estimated at 0.3 mg/dl (0.03 g/L).

Precision:

Within Run N = 20	Mean *(mg/dl)*	*SD*	*% CV*	*Between Run N = 20*	Mean *(mg/dl)*	*SD*	*% CV*
Level 1	39.6	0.42	1.07	Level 1	38.2	1.30	3.58
Level 2	63.2	0.90	1.42	Level 2	61.4	1.35	2.20

Method Comparison:
Using 50 samples, a comparison, between this APO B test (y) and another commercially available test (x), gave the following results:

y = 0.842x + 10.151	r = 0.964	Sample range: 52 to 162 mg/dl

BIBLIOGRAPHY:

1. Karl J, Engel WD. Determination of Apolipoprotein A1 and B without sample dilution. Poster presented at the 57th meeting of the European Atherosclerosis Society, Lisbon and the IX European Congress of Clinical Chemistry, Cracow 1991.
2. Burtis CA, Ashwood ER. Tietz Fund. Of Clin. Chem. 5th ed. 30-54, 462-494 and 965.
3. Guder WG, Narayanan S, Wisser H, Zawta B. The Quality of Diagnostic Samples. Brochure in: Samples: From the Patient to theLaboratory, 2nd edition. Darmstadt: GIT-Verlag, 2001.

SYMBOLS:

The following symbols are used in the labelling of Glenbio systems:

IVD	In Vitro Diagnostics	REF	Catalogue No
LOT	Batch Code	CONT	Content
REAG	Reagent	Ab	Antibody
CAL	Calibrator	BUF	Buffer
CE	CE Mark - Device comply with the Directives 98/79/EC		
	Storage temperature	→	Reconstitute with
	Expiry Date (Last day of the month)		Manufactured By
	Biological risk		Consult Instruction for Use

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