APOLIPOPROTEIN B

Turbidimetry

CE

IVD

REF. 6718 40+10 ml

Azienda certificata DNV

GIESSE DIAGNOSTICS

INTENDED USE

Quantitative determination of Apolipoprotein B in serum and plasma.

PRINCIPLE

Anti Apo B antibodies, when mixed with samples containing Apo B, form insoluble complexes. These complexes cause an absorbance change, dependent upon the Apo B concentration of the patient sample, that can be quantified by comparison from a calibrator of known Apo B concentration.

SAMPLE

Fresh serum, plasma with EDTA or Heparin.
The samples with presence of fibrin should be centrifuged before testing.
Do not use highly hemolized or lipemic samples.
The samples are stable 2 weeks at 2-8°C or 3 months at -20°C.

KIT COMPONENTS

Reagent (A) APO B Diluent Volume = 40 ml	Tris buffer 20 mmol/l, PEG , pH 8.3 Sodium azide 0.95 g/l
Reagent (B) APO B Antibody Volume = 10 ml	Goat serum, anti-human Apo B, Tris 50 mmol/l, pH 7.5 Sodium azide 0.95 g/l

Optional: Apolipoproteins A1/B Calibrator – REF. 7768

The Calibrator is not included in the kit.

Calibrator Volume = 1 ml	**APO A1/ B Calibrator REF. 7768**

The reagents are stable until the expiration date indicated on the label if stored tightly closed at 2-8°C . Once opened, the reagents are stable at least 3 weeks at 2-8°C protected from light and in the absence of contamination.
keep bottles closed when not in use.

REAGENT PREPARATION

Reagents are ready to use.

Calibration curve: Prepare the following dilutions of the Calibrator using NaCl 9 g/l as diluent.

Multiply the concentration of the Apo B calibrator by the corresponding factor stated in the below table to obtain the Apo B concentration of each dilution.

Dilution Cal	1	2	3	4	5	6
Calibrator (µl)	--	10	25	50	75	100
NaCl 9 g/l (µl)	100	90	75	50	25	--
Factor	0	0.1	0.25	0.5	0.75	1.0

PRECAUTIONS AND WARNINGS

Reagent may contain some non-reactive and preservative components. It is suggested to handle carefully it, avoiding contact with skin and swallow.
Use the normal precautions required in the laboratory.
Dispose of waste according to local laws.

PROCEDURE

Wavelength:	340 nm
Lightpath:	1 cm
Temperature:	37°C

Adjust the instrument to zero with distilled water

pipette:	**sample**	**calibrator**
Reagent (A)	800 µl	800 µl
sample	7 µl	
calibrator		7 µl

Mix and read the absorbance A1 after the sample addition.
Add immediately:

Reagent (B)	200 µl	200 µl

Mix and read the absorbance A2 of calibrators and sample exactly 2 minutes after the Reagent (B) addition.

RESULTS CALCULATION

Calculate the absorbance different (A2 – A1) of each point of the calibration curve and plot the values obtained against the di Apo B concentration of each calibrator dilution. di Apo B concentration in the sample is calculated by interpolation of its (A2 – A1) in the calibration curve.

EXPECTED VALUES

69 – 105 mg/dl

Each laboratory should establish appropriate reference intervals related to its population.

QUALITY CONTROL

You must perform the controls at each kit's use and verify that the values obtained are within the reference range reported in the operating instructions.
For this purpose we recommend the use of control serum:
APO A1/B Control (REF. 7769).

PERFORMANCE

Sensitivity: the sensitivity of the method is: 3.02 mg/dl. Values less than 3.02 mg/dl give non-reproducible results.

Linearity: the method is linear up to 250 mg/dl. For higher values, dilute 1:5 with saline the samples and multiply the result by 5.

Precision intra-assay:

	Level 1	Level 2	Level 3
Mean (mg/dl)	23.92	59.08	119.07
CV %	2.0	1.4	1.0

Precision inter-assay:

	Level 1	Level 2	Level 3
Mean (mg/dl)	23.92	59.08	119.07
CV %	3.7	2.2	1.8

Interferences: bilirubin does not interfere up to 40 mg/dl. Lipemia up to 2.5 g/l , Hemoglobin up to 20 g/l and Rheumatoid factors up to 800 U/ml do not interfere.

Correlation against a reference method: Y = 0.996x + 5.112 r = 0.982

REFERENCES

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