α_1- ACID GLYCOPROTEIN

Turbidimetry

REF. 6703 40+10 ml

CE
IVD

Azienda certificata DNV

GIESSE DIAGNOSTICS

INTENDED USE

Quantitative determination of α_1- acid glycoprotein in serum and plasma.

PRINCIPLE

Anti- α_1- acid glycoprotein antibodies when mixed with samples containing α_1- acid glycoprotein form insoluble complexes. These complexes cause an absorbance change, dependent upon the α_1- acid glycoprotein concentration of the patient sample, that can be quantified by comparison from a calibrator of known α_1- acid glycoprotein concentration.

SAMPLE

Fresh serum, plasma with Heparin or EDTA.

The samples with presence of fibrin should be centrifuged. Do not use highly hemolized or lipemic samples.

The samples are stable 7 days at 2-8°C or 3 months at -20°C.

KIT COMPONENTS

Reagent (A) Diluent Volume = 40 ml	Tris buffer 20 mmol/l, PEG 8000, pH 8.3 Sodium azide 0.95 g/l
Reagent (B) Antibody Volume = 10 ml	Goat serum, anti -human α_1- acid glycoprotein, pH 7.5 Sodium azide 0.95 g/l

Optional: General Proteins Calibrator – REF. *7779*

The Calibrator is not included in the kit.

Calibrator Volume = 2 ml	**General Proteins Calibrator REF. *7779***

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 α_1- acid glycoprotein calibrator by the corresponding factor stated in the below table to obtain the α_1- acid glycoprotein concentration of each dilution.

Cal Dilution	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	10 µl	
calibrator		10 µl

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

Reagente (B)	200 µl	200 µl

Mix and read the absorbance A2 of calibrators and sample exactly 4 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 α_1- acid glycoprotein concentration of each calibrator dilution. α_1- acid glycoprotein concentration in the sample is calculated by interpolation of its (A2 – A1) in the calibration curve.

EXPECTED VALUES

50 – 120 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:

General Proteins Control (REF. *7767*).

PERFORMANCE

Sensitivity: the sensitivity of the method is: 12.9 mg/dl. Values less than 12.9 mg/dl give non-reproducible results.

Prozone effect: No prozone effect up to 1000 mg/dl.

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

Precision intra-assay:

	Level 1	Level 2
Mean (mg/dl)	56.4	112.07
CV %	1.1	1.6

Precision inter-assay:

	Level 1	Level 2
Mean (mg/dl)	56.4	112.07
CV %	3	2.1

Interferences: bilirubin does not interfere up to 20 mg/dl. Hemoglobin up to 10 g/l, lipemia up to 2.5 g/l and Rheumatoid factors up to 200 U/ml do not interfere.

Correlation against a reference method: Y = 0.930x + 6.5367 r = 0.95

REFERENCES

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