

α_1 -ANTITRYPSIN

Turbidimetry

REF. 6702 40+10 ml



Azienda certificata DNV



INTENDED USE

Quantitative determination of α_1 -antitrypsin in serum and plasma.

PRINCIPLE

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

SAMPLE

Fresh serum, plasma with EDTA or Heparin.

Do not use highly hemolyzed or lipemic samples.

The sample 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 -antitrypsin, 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.

REAGENTS PREPARATION

The reagent 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 -antitrypsin calibrator by the corresponding factor stated in the below table to obtain the α_1 -antitrypsin concentration of each dilution.

Cal Dilution	1	2	3	4	5	6
Calibrator (μ l)	--	10	25	50	75	100
NaCl 9 g/l (μ l)	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 μ l	800 μ l
sample	10 μ l	
calibrator		10 μ l

Mix and read the absorbance A1 after the sample addition.

Add immediately:

Reagent (B)	200 μ l	200 μ l
-------------	-------------	-------------

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 α_1 -antitrypsin concentration of each calibrator dilution. α_1 -antitrypsin concentration in the sample is calculated by interpolation of its (A2 – A1) in the calibration curve.

EXPECTED VALUES

Newborn: 124 – 348 mg/dl
Adults: 90 – 200 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:

Generale Proteins Control (REF. 7767).

PERFORMANCE

Sensitivity: the sensitivity of the method is: 16 mg/dl. Values under 16 mg/dl give non-reproducible results.

Prozone effect: No prozone effect up to 750 mg/dl.

Linearity: the method is linear up to 400 mg/dl. For higher values, dilute the sample 1:5 and multiply the result by 5.

Precision intra-assay:

	Level 1	Level 2	Level 3
Mean (mg/dl)	34.39	92.7	181.8
CV %	0.8	1.1	1.6

Precision inter-assay:

	Level 1	Level 2	Level 3
Mean (mg/dl)	34.39	92.7	181.8
CV %	3.8	2.4	2.3

Interferences: bilirubin does not interfere up to 40 mg/dl. Hemoglobin up to 8 g/l, lipemia up to 16 g/l and Rheumatoid factor up to 790 U/ml do not interfere.

Correlation against a reference method: $Y = 0.84x + 26.5$ $r = 0.92$

REFERENCES

1. Clinical Guide to Laboratory Tests, Edited by NW Tietz W.B. Saunders Co., Philadelphia, 483 (1983).
2. Dati F. et al. Eur J Clin Chem Clin Biochem 1996; 34:517-520
3. Pesce AJ and Kaplan, LA. Methods in Clinical Chemistry. The CV Mosby Company, St. Louis MO, (1987).
4. Sharp HL Hospital Practice; May 83-96 (1971).
5. Carrel RW et al. Assay Med Biochem 4:83-119 (1978).
6. Young DS. Effects of drugs on Clinical Laboratory Tests, 4th ed. AAC Press (1995).
7. Friedman and Young. Effects of disease on Clinical Laboratory tests, 3th ed. AAC Press (1997).