CORMAY ALPHA 1-ANTITRYPSIN

DIAGNOSTIC KIT FOR DETERMINATION OF α 1-ANTITRYPSIN CONCENTRATION

Kit name	Kit size	Cat. No
CORMAY ALPHA 1-ANTITRYPSIN	1 x 58.5 ml	4-591

INTRODUCTION

α 1-antitrypsin is an acute phase protein showing anti-protease activity. The main function of this protein consists in neutralising lysosomal elastase released upon phagocytosis by polymorphonuclear leukocytes. Inherited deficiency of the protein is associated with lung and liver diseases. Low levels are encountered in neonatal respiratory distress syndrome and in severe protein losing disorders. Increased levels are more common, particularly during the acute phase.

METHOD PRINCIPLE

The α 1-antitrypsin presents in a sample form with the specific antibody an immunological complex. The increase of turbidity after the addition of antiserum measured at λ=340 nm is proportional to α 1-antitrypsin concentration in the sample.

REAGENTS

Package

1-Reagent	1 x 48.5 ml
2-Reagent	1 x 10 ml

Buffer (1-Reagent) and antiserum (2-Reagent) stored at 2-8°C are stable until expiry date printed on the package. Protect from light and avoid contamination!

Concentrations in the test

TRIS buffer (pH 8); PEG; sodium chloride; anti human α 1-antitrypsin antiserum; HEPES buffer (pH 7.4); stabilizers; detergents.

Warnings and notes

- Products for in vitro diagnostic use only.
- The reagents must be used only for the intended purpose, by suitably qualified laboratory personnel, under appropriate laboratory conditions.
- Do not use after expiry date.
- Do not interchange caps.
- Reagent should be mixed before use by gentle inverting the bottle several times!
- The appearance of turbidity or control sera values outside the manufacturer's acceptable range may indicate of reagent instability.

ADDITIONAL EQUIPMENT

- automated clinical chemistry analyser capable of accommodating two-reagent assays;
- general laboratory equipment;

SPECIMEN

Serum or plasma (EDTA).
Sample may be stored up to 24 hours at 20-25°C, up to 7 days at 4-8°C or up to 3 months at -70ºC.
Nevertheless it is recommended to perform the assay with freshly collected samples!

PROCEDURE

The reagents are ready to use.
These reagents may be used in automatic analysers according to their user manual. Applications for analysers are available on request.
These reagents may be used directly in Hitachi 911/912 analysers.
Application should be entered using handheld barcode scanner and attached barcodes sheet, according to procedure described below:

1. Delete previous version of application and calibrators assigned to it and restart the analyser.
2. Enter codes of calibrators according to the attached list.
3. Enter barcoded application and assign proper values to calibrators.
4. To activate entered application go to the tab UTILITY | APPLICATION | RANGE and change value of field DATA MODE from INACTIVE to ON BOARD. Confirm the change using UPDATE button.
5. Put reagents on board the analyser – they will be assigned to relevant tests automatically. Perform also measurement of level of reagents inside the bottles.
6. After calibration analyser is ready to use.

REFERENCE VALUES [3]

adults	0.78 – 2.00 g/l
newborns	1.45 – 2.70 g/l

It is recommended for each laboratory to establish its own reference ranges for local population.

QUALITY CONTROL

For internal quality control it is recommended to use the CORMAY IMMUNO-CONTROL III (Cat. No 4-291) with each batch of samples.
For the calibration of automatic analysers systems the CORMAY IMMUNO-MULTICAL (Cat. No 4-287) is recommended. **Calibrators and 0.9% NaCl** should be used for calibration.
The calibration curve should be prepared every 4 weeks, with change of reagent lot number or as required e.g. quality control findings outside the specified range.

PERFORMANCE CHARACTERISTICS

These metrological characteristics have been obtained using the automatic analyser Hitachi 917. Results may vary if a different instrument is used.

- **Measurement range:** 0.007 g/l to 3.50 g/l.

- **Interferences:**

Hemoglobin up to 0.322 g/dl, bilirubin up to 29.5 mg/dl, triglycerides up to 1682 mg/dl, heparin up to 0.5 g/l, sodium fluoride up to 4 g/l, EDTA up to 5 g/l, sodium citrate up to 5 g/l do not interfere with the test.

- **Precision**

Repeatability (run to run) n = 30	Mean [mg/dl]	SD	CV [%]
level 1	58.3	0.7	1.1
level 2	117.7	1.0	0.9
level 3	176.7	2.0	1.1

- **Method comparison**

A comparison between CORMAY reagent (y) and commercially available assay (x) using 40 samples gave following results:
y = 0.9668 x + 3.6562 mg/dl;
R = 0.9786 (R – correlation coefficient)

WASTE MANAGEMENT

Please refer to local legal requirements.

LITERATURE

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MANUFACTURER

PZ CORMAY S.A.
ul. Wiosenna 22,
05-092 Łomianki, POLAND
tel.: +48 (0) 22 751 79 10
fax: +48 (0) 22 751 79 14
http://www.pzcormay.pl

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