Cat. No 9-443

DIAGNOSTIC KIT FOR DETERMINATION OF α 1-ANTITRYPSIN CONCENTRATION

OS – ALPHA 1-ANTITRYPSIN

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 is proportional to α 1-antitrypsin concentration in the sample.

REAGENTS
Package

1-Reagent	1 x 45.5 ml
2-Reagent	1 x 9 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.
- Products from human source have been tested for the HBsAg and antibodies to HIV and HCV and found to be non-reactive. However this material should be handled as thought capable of transmitting infectious disease.
- Products contain sodium azide (< 1 g/l) as a preservative. Avoid contact with skin and mucous membranes.

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
These reagents may be used in automatic analysers Olympus AU400/AU640.
1-Reagent and 2-Reagent are ready to use.
For reagent blank 0.9% NaCl is recommended.

APPLICATION
Reagent ID: **063**

Specific Test Parameters

General | LIH | ISE | Range

Test name: **ATT** Type: **Serum** Operation: **Yes**

Sample: Volume	2	µL	Dilution	0	µL	Pre-Dilution Rate:	1		
Reagents: R1 Volume	210	µL	Dilution	0	µL	Min OD		Max OD	
R2 Volume	30	µL	Dilution	0	µL	L	-2.0000	H	2.5000
						Reagent OD Limit:			
Wavelength: Pri.	340	Sec.	700			First L	-2.0000	First H	2.5000
Method:	END					Last L	-2.0000	Last H	2.5000
Reaction Slope:	+					Dynamic Range:			
Measuring Point 1: First	0	Last	27			L		H	
Measuring Point 2: First	0	Last	10			Correlation Factor:			
Linearity:		%				A	1.000	B	0.000
No-Lag-Time:						On-board Stability Period:			

Specific Test Parameters

General | LIH | ISE | Range

Test name: **ATT** Type: **Serum**

Value/Flag: # Level L: # Level H: #

Normal Ranges:

	Sex	Age L Year	Age L Month	Age H Year	Age H Month	L	H
1.	#	#	#	#	#	#	#
2.	#	#	#	#	#	#	#
3.	#	#	#	#	#	#	#
4.	#	#	#	#	#	#	#
5.	#	#	#	#	#	#	#
6.	#	#	#	#	#	#	#
7. None Selected						#	#
8 Out of Range						#	#

Panic Value: L # H # Unit: **g/l** Decimal Places: **2**

Calibration Specific

General | ISE

Test name: **ATT** Type: **Serum**

Calibration Type: **6AB** Formula: **Spline** Counts: **1** Process: **CONC**

	Cal. No.	OD	CONC	Factor/OD-L	Factor/OD-H
Point 1:	#		**	-2.0000	2.5000
Point 2:	#		*	-2.0000	2.5000
Point 3:	#		*	-2.0000	2.5000
Point 4:	#		*	-2.0000	2.5000
Point 5:	#		*	-2.0000	2.5000
Point 6:	#		*	-2.0000	2.5000
Point 7:					

1-Point Cal.Point: with CONC-0 Slope Check: **None** Advanced Calibration: #

MB Type Factor: Calibration Stability Period:

\# User defined
* Calibrator value
** Saline should be used as calibrator 1

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.
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 or manual procedure 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 = 0.9668x + 3.6562 mg/dl;
R = 0.9786 (R – correlation coefficient)

WASTE MANAGEMENT

Please refer to local legal requirements.

LITERATURE

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