Cat. No 9-442

DIAGNOSTIC KIT FOR DETERMINATION OF α 1-GLYCOPROTEIN ACID CONCENTRATION

OS – ALPHA 1-GLYCOPROTEIN ACID

INTRODUCTION
α 1-glycoprotein acid (orosomucoid) is unique amongst plasma proteins because of its low pH and high carbohydrate content. The protein is a serum transporter for steroid hormone and for many drugs. Its physiological role remains unknown but it is an acute phase reactant. The concentration of this protein in serum is used clinically to monitor acute phase responses and tumour recurrence.

METHOD PRINCIPLE
The α 1-glycoprotein acid 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-glycoprotein acid concentration in the sample.

REAGENTS
Package

1-Reagent	1 x 36 ml
2-Reagent	1 x 9 ml

Buffer (1-Reagent) stored at 2-25°C 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
Glycylglycin buffer (pH 8.5); PEG; sodium chloride; anti human α 1-glycoprotein acid antiserum; HEPES buffer (pH 7.4); stabilizers.

Warnings and notes
- Products for in vitro diagnostic use only.
- The reagents must be used only for the purpose intended by suitably qualified laboratory personnel, under appropriate laboratory conditions.
- Products from human source have been tested for 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 (< 0.1%) as a preservative. Avoid contact with skin and mucous membranes.

SPECIMEN
Serum.
Specimen without lipemia or hemolysis is recommended.
Serum can be stored up to 6 hours at room temperature or up to 3 days at 2-8ºC or up to 3 months at (-15) to (-20)ºC.
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: **062**

Specific Test Parameters

General | LIH | ISE | Range

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

Sample: Volume	2	µL	Dilution	0	µL	Pre-Dilution Rate:	1	
Reagents: R1 Volume	160	µL	Dilution	0	µL	Min OD	Max OD	
R2 Volume	32	µL	Dilution	0	µL	L -2.0000	H 2.5000	
						Reagent OD Limit:		
Wavelength: Pri.	340		Sec.	410		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: **AGP** 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						#	#

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

Calibration Specific

General | ISE

Test name: **AGP** 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 [4]

serum	0.39 – 1.15 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 an automatic analyser Cobas Mira. Results may vary if a different instrument is used.

- **Analytical range:** 0.037 g/l to 2 g/l.

- **Interferences:**

Haemoglobin up to 0.32 g/dl, bilirubin up to 29.5 mg/dl, triglycerides up to 2000 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 = 10	Mean [mg/dl]	SD	CV [%]
level 1	47.0	0.6	1.2
level 2	72.0	0.9	1.3
level 3	89.9	1.3	1.4

Reproducibility (day to day) n = 10	Mean [mg/dl]	SD	CV [%]
level 1	41.5	1.0	2.3
level 2	61.6	1.3	2.2
level 3	46.3	0.9	2.0
level 4	69.3	4.5	6.5
level 5	93.2	1.7	1.8

- **Method comparison**

A comparison between CORMAY reagent (y) and another commercially available assay (x) using 17 samples gave following results:
y = 0.93 x + 10.5 mg/dl;
R = 0.8894 (R – correlation coefficient)

WASTE MANAGEMENT
Please refer to local legal requirements.

LITERATURE

1. Bergstrom, K. & Lefvert, A.K.: Scand.J.clin.Lab.Invest. 40 (1980), 637.
2. Tietz Textbook of Clinical Chemistry, W.B. Saunders, Philadelphia, (1994).
3. Roitt, I.: Essential Immunology, Blackwell, Oxford, (1991).
4. Alan H.B. Wu. editor. Tietz Clinical Guide to Laboratory Tests, 4th ed. St. Louis: W.B Saunders Company; (2006), 42.
5. Procedures for the Handling and Processing of Blood Specimens; Approved Guideline-Third Edition, H18-A3, Vol. 24 No. 38, Replaces H18-A2, Vol. 19 No. 21.

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