# DIAGNOSTIC KIT FOR DETERMINATION OF α 1-GLYCOPROTEIN ACID CONCENTRATION

# OS – ALPHA 1-GLYCOPROTEIN ACID

## INTRODUCTION

 $\alpha$  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  $\alpha$  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  $\lambda=340$  nm is proportional to  $\alpha$  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  $\alpha$  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.</li>
  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 2-8°C or up to 3 months at (-15) to (-20)°C.

Nevertheless it is recommended to perform the assay with freshly collected samples!

## **PROCEDURE**

These reagents may be used in automatic analysers Olympus AU400/AU640.

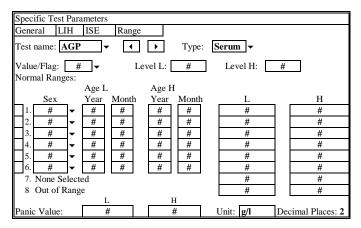
1-Reagent and 2-Reagent are ready to use.

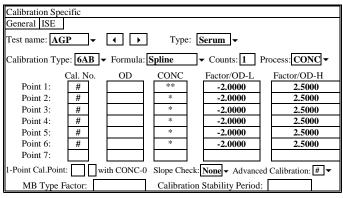
For reagent blank 0.9% NaCl is recommended.



## APPLICATION

Reagent ID: 062 Specific Test Parameters LIH ISE Range General **←** Test name: AGP Type: Serum ▼ Operation: Yes ▼ Sample: Volume uL Dilution 0 μL Pre-Dilution Rate: 1 Reagents: R1 Volume 160 μL Dilution μL Min OD R2 Volume 32 μL Dilution 0 L **-2.0000** H 2.5000 Reagent OD Limit: Pri. 340 Sec. 410 First L -2.0000 First H 2.5000 Wavelength: Method: END Last L -2.0000 Last H 2.5000 Reaction Slope: Dynamic Range: Measuring Point 1: First 0 Last L Measuring Point 2: First 0 Last 10 Correlation Factor: Linearity: A 1.000 В 0.000 No-Lag-Time: On-board 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.

## **OUALITY 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

- Bergstrom, K. & Lefvert, A.K.: Scand.J.clin.Lab.Invest. 40 (1980), 637.
- 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.
- 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.

**Date of issue:** 05. 2016.

## MANUFACTURER

## PZ CORMAY S.A.

22 Wiosenna Street, 05-092 Łomianki, POLAND tel.: +48 (0) 22 751 79 10 fax: +48 (0) 22 751 79 14 http://www.cormay.pl