CORMAY ALPHA 1-GLYCOPROTEIN ACID

DIAGNOSTIC KIT FOR DETERMINATION OF α 1-GLYCOPROTEIN ACID CONCENTRATION

Kit name	Kit size	Cat. No
CORMAY ALPHA 1-GLYCOPROTEIN ACID	1 x 58.5 ml	4-590

INTRODUCTION

α1-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 α1-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 α1-glycoprotein acid concentration in the sample.

REAGENTS

Package

1-Reagent	1 x 48.5 ml
2-Reagent	1 x 10 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. On board stability of the reagents depends on type of analyser used for analysis. Protect from light and avoid contamination!

Concentrations in the test

Glycylglycin buffer (pH 8.5); PEG; sodium chloride; anti human α1-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 intended purpose, 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.

ADDITIONAL EQUIPMENT

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

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

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 [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. Calibrators and 0.9% NaCl should be used for calibration.
Calibration stability depends on type of analyser used for analysis The calibration curve should be prepared 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 analysers Hitachi 912 and Cobas Mira. Results may vary if a different instrument is used.

- **Sensitivity:** 0.08 g/l.
- **Linearity:** up to 2 g/l.
- **Specificity / 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 [g/l]	SD [g/l]	CV [%]
level 1	0.82	0.01	1.58
level 2	1.73	0.01	0.79

Reproducibility (day to day) n = 10	Mean [g/l]	SD [g/l]	CV [%]
level 1	0.42	0.01	2.3
level 2	0.62	0.01	2.2
level 3	0.46	0.01	2.0
level 4	0.69	0.05	6.5
level 5	0.93	0.02	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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