CORMAY CERULOPLASMIN

DIAGNOSTIC KIT FOR DETERMINATION OF CERULOPLASMIN CONCENTRATION

Kit name	Kit size	Cat. No
CORMAY CERULOPLASMIN	1 x 58.5 ml	4-588

INTRODUCTION

Ceruloplasmin is an α2-glycoprotein containing 6-7 atoms of copper per molecule. It has been considered for a long time as a copper transporter but since recently, it has been shown to be a serum ferroxidase playing a major role in oxidising iron (II) to iron (III) in serum and at the cell surface, thereby regulating its binding by transferrin.
Ceruloplasmin is a late acute phase reactant. Low levels are found in malnutrition, nephrosis, severe liver diseases such as primary biliary cirrhosis and in Wilson's disease, an autosomal recessive defect in the regulation of copper metabolism.

METHOD PRINCIPLE

The ceruloplasmin presents in a sample form with the specific antibody an immunological complex. The increase of turbidity after the addition of antiserum measured spectrophotometrically at λ=340 nm is proportional to ceruloplasmin 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. Store closed. Protect from light and avoid contamination!

Concentrations in the test

MES buffer (pH 6.5); PEG; sodium chloride; anti human ceruloplasmin 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.

ADDITIONAL EQUIPMENT

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

SPECIMEN

Serum.
Specimen without lipemia or hemolysis is recommended.
Samples remain stable for 3 days at 2-8°C or 4 weeks at -20°C.
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 [7]

age	g/l	mg/dl
1 day – 3 months	0.05 – 0.18	5 – 18
6 – 12 months	0.33 – 0.43	33 – 43
1 – 7 years	0.24 – 0.56	24 – 56
> 7 years	0.18 – 0.45	18 – 45

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 analysers Cobas Mira. Results may vary if a different instrument is used.

- **Analytical range:** 0.006 – 1 g/l (0.6 – 100 mg/dl).

- **Specificity / Interferences**

Hemoglobin up to 0.32 g/dl, bilirubin up to 22 mg/dl triglycerides up to 1000 mg/dl, heparin up to 0.3 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 [mg/dl]	CV [%]
level 1	17.9	0.2	0.9
level 2	31.4	0.6	2.0
level 3	43.8	1.5	3.5

Reproducibility (day to day) n = 10	Mean [mg/dl]	SD [mg/dl]	CV [%]
level 1	17.5	0.7	4.1
level 2	31.0	1.1	3.5
level 3	46.1	0.9	1.9

- **Method comparison**

A comparison between CORMAY reagent (y) and commercially available assay (x) using 31 samples gave following results:
y = 0.82 x + 2.82 mg/dl;
R = 0.9165 (R – correlation coefficient)

WASTE MANAGEMENT

Please refer to local legal requirements.

LITERATURE

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