Cat. No 9-441

# DIAGNOSTIC KIT FOR DETERMINATION OF CERULOPLASMIN CONCENTRATION

## OS – CERULOPLASMIN

### INTRODUCTION
Ceruloplasmin is an α 2-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 at λ=340 nm is proportional to ceruloplasmin 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. 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 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 (< 0.1%) as a preservative. Avoid contact with skin and mucous membranes.

### 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
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: **064**

Specific Test Parameters
General | LIH | ISE | Range

Test name: CERU  Type: Serum  Operation: Yes

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| Sample: | Volume | 3.5 | 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. | 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: CERU  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: 3

Calibration Specific
General | ISE

Test name: CERU  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 [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.

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 Cobas Mira. Results may vary if a different instrument or manual procedure 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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