CORMAY HAPTOGLOBIN

DIAGNOSTIC KIT FOR DETERMINATION OF HAPTOGLOBIN CONCENTRATION

Kit name	Kit size	Cat. No
CORMAY HAPTOGLOBIN	1 x 58.5 ml	4-587

INTRODUCTION

Haptoglobin is an acute phase protein whose primary function consists in binding free haemoglobin in serum. The complex is removed within minutes by the reticulo-endothelial system where its components are metabolised to free aminoacids and iron. Haptoglobin consequently plays a major role in preventing the loss of haemoglobin in urine and the consequent iron loss from the iron pool. The haptoglobin levels are increased during the acute phase and in such conditions as burns or nephrotic syndrome. Haptoglobin levels are abnormally high in intravascular hemolysis and when haemoglobin turnover is increased such as during haemolytic anaemia, transfusion reactions and malaria.

METHOD PRINCIPLE

The haptoglobin 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 haptoglobin 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

Imidazole buffer (pH 7.0); PEG; sodium chloride; anti human haptoglobin 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.
Sample may be stored several days at 2-8°C. Samples frozen at -20ºC can be stored longer.
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]

adults	0.26 – 1.85 g/l
newborns	0.05 – 0.48 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.
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 is used.

- **Analytical range:** 0.05 g/l do 4 g/l.

- **Interferences:**

Hemoglobin 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	55.9	0.7	1.3
level 2	110.8	1.2	1.1
level 3	137.7	1.5	1.1

Reproducibility (day to day) n = 10	Mean [mg/dl]	SD	CV [%]
level 1	60.0	2.1	3.6
level 2	113.0	4.6	4.1
level 3	141.1	4.9	3.5

- **Method comparison**

A comparison between CORMAY reagent (y) and another commercially available assay (x) using 68 samples gave following results:
y = 0.86 x + 11.1 mg/dl;
R = 0.946 (R – correlation coefficient)

WASTE MANAGEMENT
Please refer to local legal requirements.

LITERATURE

1. Kaplan L.A., Pesce A.J.: Clinical Chemisty, Third Edition, Mosby, 731 (1996).
2. Jacobs, D. S. et al., Laboratory test Handbook, Mosby, St Louis, (1984).
3. Tietz Textbook of Clinical Chemistry, W.B. Saunders, Philadelphia, (1994).
4. Alan H.B. Wu, ed.: Tietz Clinical Guide to Laboratory Tests, 4th ed. W.B. Saunders Company., 512, (2006).

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