DIAGNOSTIC KIT FOR DETERMINATION OF HAPTOGLOBIN CONCENTRATION

OS – HAPTOGLOBIN

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 35.5 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 and avoid contamination.

Concentrations in the test

Imidazole buffer (pH 7.0); PEG; sodium chloride; anti human haptoglobin antiserum; HEPES buffer (pH 7.4); sodium azide (< 1 g/l); 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 the HIV antibody, HbsAg 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 (< 1 g/l) as a preservative. Avoid contact with skin and mucous membranes.

SPECIMEN

Serum.

Sample may be stored several days at 2-8°C. Samples frozen at -20°C can be stored longer.

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

PROCEDURE

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

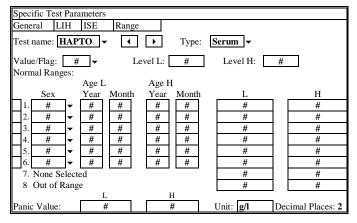
1-Reagent and 2-Reagent are ready to use.

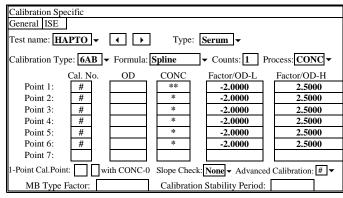
For reagent blank 0.9% NaCl is recommended.



APPLICATION

Reagent ID: 065 Specific Test Parameters LIH ISE Range General **←** Test name: HAPTO ▼ Type: Serum ▼ Operation: Yes ▼ μL Dilution 0 Sample: Volume μL Pre-Dilution Rate: 1 Reagents: R1 Volume μL Dilution 0 μL Min OD R2 Volume 32 μL Dilution 0 L **-2.0000** H 2.5000 Reagent OD Limit: Wavelength: Pri. 340 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 Measuring Point 2: First 0 Correlation Factor: Last 10 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

REFERENCE VILLER		
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. 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 or manual procedure 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 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

- Kaplan L.A., Pesce A.J.: Clinical Chemisty, Third Edition, Mosby, 731 (1996).
- 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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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

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