Cat. No 9-440

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^{0}C. Samples frozen at -20ºC 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

General | LIH | ISE | Range

Test name: **HAPTO** Type: **Serum** Operation: **Yes**

Sample:	Volume	7	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: **HAPTO** 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: **2**

Calibration Specific

General | ISE

Test name: **HAPTO** 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 [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. 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

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).

Date of issue: 05. 2016.

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05/16/05/16