Haptoglobin KIT

Quantitative determination of Haptoglobin (HAP) in human serum by turbidimetric immunoassay according to the procedure R1: 250 µL and R2: 50 µL.

Code Kit	Contents Kit
119C004	1 x 10 mL Antiserum 2 x 25 mL Buffer

Key Reference
119R00: partial code, used as product reference in catalogues and all technical documents.

Diagnostic Implications
Acute phase protein. Transport molecule for haemoglobin. Increased levels of HAP are reported in acute inflammation, collagenoses, coronary disorders, Hodgkin's disease, nephrotic syndrome and tuberculosis. Decreased levels of HAP are found in haemolytic anaemia, liver disease, congenital deficiencies and acute malaria.

Method
Measurement of antigen-antibody reaction by the end-point method.

Reagents Provided
Antiserum
Phosphate buffered saline.
Polyclonal goat anti-human Haptoglobin (variable).
Sodium azide (0.95 g/L).
Buffer
Phosphate buffered saline.
Enhancer.
Sodium azide (0.95 g/L).

Preparation and Stability of Reagents
Reagent Preparation
Liquid reagents, ready for use.
Stability and Storage
The reagents are stable until expiry date when kept at 2-8°C. Stability in the instrument is at least 4 weeks if contamination is avoided. Do not freeze.

Reagents required but not supplied
1. Saline (9 g/L)
2. Calibrators and Controls *

Code	Description
MPS/STH-001	Protein Standard High, 1 mL
MPS/STS-5X1	Protein Standard Set, 5 x 1 mL
139F003	Immunology Control Low, 1 mL
139F002	Immunology Control High, 1 mL

* Also available in other packsizes.

Pooled human serum, liquid and stabilized. Contains 0.95 g/L sodium azide. Value is stated in the insert.

Sample collection
Use fresh serum. If the test can not be carried out on the same day, the serum may be stored at 2 - 8°C for 48 hours. If stored for a longer period, the sample should be frozen.

General Assay Procedure*
Application sheets for automated systems on clinical chemistry analyzers or manual procedures are available upon request.
Wavelength 340nm

Sample, Control or calibrator	2µL
Add Reagent 1	250µL
Mix, incubate for 2 minutes, read absorbance, then add Reagent 2	50µL
Mix, incubate and read absorbance after 5 minutes.	

*validated on Pentra 400 device.

Reference Values
32-205 mg/dL (IFCC)
This range is given for orientation only. Each laboratory should establish its own reference range.

Performances
The performance characteristics for the Haptoglobin reagents were measured on a clinical chemistry analyzer.

Measuring Range: 0 - 351 mg/dL
Detection Limit: 1.8 mg/dL
Hookeffect: > 600 mg/dL
Sensitivity: 23.8 ABS units / concentration unit

Precision: [%CV]

	Low	Medium	High
Intra-Run	3.51	2.40	5.23
Inter-Run		1.99	

Accuracy: [mg/dL]

Control	Assigned	Measured
APTEC	116 (99-134)	117
Biorad 1	66 (56-76)	68
Biorad 2	135 (114-155)	147

Specificity: Monospecific
Limitations: None
Stability at 2-8°C: At least 3 years after production

Precautions and warnings
1. In vitro diagnostic use only.
2. Sodium azide has been reported to form lead or copper azide in laboratory plumbing which may explode on percussion. Flush drains with water thoroughly after disposing of fluids containing sodium azide.
3. Polyethylene glycol is non biohazardous.
4. Each donor unit used in the preparation of the standards and controls was found to be negative for the presence of HIV1 and HIV2 antibodies, as well as for the hepatitis B surface antigen and anti-hepatitis C antibodies, using a method approved by the FDA.

References
1. Dati, F. et al., Lab. Med. 13, 87 (1989)

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