Clinical Chemistry

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REF A11A01697

REAGENT 1 x 5 mL

IVD CE

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FRANCE

ABX Pentra Haptoglobin

- ABX Pentra 400

Diagnostic reagent for quantitative *in vitro* determination of Haptoglobin in serum or plasma by immunoturbidimetry.

Application Release [a]

Serum, plasma: HAPT (not for use in the USA)

4.xx

Intended Use (not for use in the USA) [a]

ABX Pentra Haptoglobin reagent is intended for the quantitative *in vitro* diagnostic determination of Haptoglobin in serum and plasma by turbidimetry.
Measurement of haptoglobin may aid in the diagnosis of hemolytic diseases (diseases in which the red blood cells rupture and release hemoglobin) related to the formation of hemoglobin-haptoglobin complexes and certain kidney diseases.

Clinical Interest (1)

Haptoglobin is a protein which binds to free haemoglobin in the vascular system for transport to the reticuloendothelial system where it is broken down. A large decrease indicates intravascular haemolysis (haemolytic anaemia) and could be associated with certain kidney disease. A large increase in the serum is caused by actute inflammation reactions.

Method (2)

Human serum or plasma is mixed with the antibody solution. The resulting immune complexes are measured turbidimetrically. The signal generated is in direct correlation with the concentration of Haptoglobin in the sample.

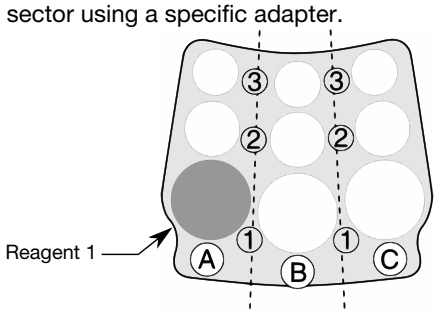
The concentration of Haptoglobin in the sample is calculated by comparison of the results on a standard curve.

Reagents

- **ABX Pentra Haptoglobin** is ready-to-use.
  It is a fraction of purified immunoglobulins: human anti-haptoglobin rabbit antibody. It contains 15 mM NaN_3 as stabiliser.
- **Immunogen:** Haptoglobin isolated from a pool of human sera.
- **ABX Pentra Haptoglobin** should be used according to this notice. The manufacturer cannot guarantee its performance if used otherwise.

Handling

1. Place the reagent directly in position 1 of one available sector using a specific adapter.



2. If present, remove foam by using a plastic pipette.

[a]Modification: chapter added.

QUAL-QA-WORI-5541 Rev.1

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3. Place the reagent rack into the refrigerated ABX Pentra 400 reagent compartment.
   After the tests, recap immediately the reagent vial and place it in a refrigerator.
4. Place the **ABX Pentra Accelerator I CP** (A11A01655) and **ABX Pentra Sample Diluent CP** (A11A01662) cassettes in the refrigerated ABX Pentra 400 reagent compartment.

Calibrator

For calibration, use:
ABX Pentra Protein Cal (A11A01698) (not included)
4 x 1 mL

Control [b]

For internal quality control, use:

- **ABX Pentra Protein Control L/H** (A11A01700) (not included)
  2 x 1 mL + 2 x 1 mL (Only the low control is titrated)
  or
- **ABX Pentra N MultiControl** (1300054414) (not included)
  10 x 5 mL (lyophilisate)
- **ABX Pentra P MultiControl** (1300054415) (not included)
  10 x 5 mL (lyophilisate)

Each control should be assayed daily and/or after a calibration.
The frequency of controls and the confidence intervals should correspond to laboratory guidelines and country-specific directives. You should follow federal, state and local guidelines for testing quality control materials. The results must be within the range of the defined confidence limits. Each laboratory should establish a procedure to follow if the results exceed these confidence limits.

Materials Required but not Provided [b]

- Automated clinical chemistry analyzer: ABX Pentra 400
- Calibrator: **ABX Pentra Protein Cal** (A11A01698)
- Controls:
  ABX Pentra Protein Control L/H (A11A01700)
  or
  ABX Pentra N MultiControl (1300054414)
  ABX Pentra P MultiControl (1300054415)
- **ABX Pentra Sample diluent CP** (A11A01662), 99 mL
- **ABX Pentra Accelerator I CP** (A11A01655), 99 mL
- Standard laboratory equipment.

Specimen [c]

- Serum.
- Plasma in EDTA.

Anticoagulants other than those listed have not been tested by HORIBA Medical and are therefore not recommended for use with this assay.

Stability:

- At 2-5°C: 1 week
- At -20°C: 1 week

Freeze only once!

Reference Range (3)

0.3-2 g/L based on CRM 470.
Each laboratory should establish its own reference ranges. The values given here are used as guidelines only.

Storage and Stability

Stability before opening:

Stable up to the expiry date on the label if stored at 2-8°C.

Stability after opening:

Stable up to the expiry date on the label if stored at 2-8°C, closed immediately and contamination is avoided.

Waste Management

- Please refer to local legal requirements.
- This reagent contains less than 0.1% of sodium azide as a preservative. Sodium azide may react with lead and copper to form explosive metal azides.

[b]Modification: new control.
[c]Modification: recommendation added.

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General Precautions [d]

- This reagent is for professional *in vitro* diagnostic use only.
- For prescription use only.
- This reagent is classified as non-hazardous in compliance with regulation (EC) N°.1272/2008.
- **Warning:** This reagent is obtained from substances of animal origin. Consequently, it should be treated as potentially infectious and handled with the appropriate cautions in accordance with good laboratory practices (4).
- Do not pipette by mouth.
- Do not replenish the reagents.
- Do not swallow. Avoid contact with skin and mucous membranes.
- Observe the standard laboratory precautions for use.
- The reagent vials are disposable and should be disposed of in accordance with the local legal requirements.
- Please refer to the SDS associated with the reagent.
- Do not use the product if there is visible evidence of biological, chemical or physical deterioration.
- It is the user's responsibility to verify that this document is applicable to the reagent used.

Performance on ABX Pentra 400

Serum, plasma

The performance data listed below have been obtained on the ABX Pentra 400 analyzer.

Number of tests: approximately 690 tests

Sample volume: 12 µL/test

Detection Limit

The detection limit is determined according to the Valtec protocol (3) and equals 0.07 g/L.

Accuracy and Precision

Repeatability (within-run precision)

Repeatability according to the recommendations found in the Valtec protocol (3) with samples tested 20 times:

- 2 controls
- 3 specimens (low / medium / high levels)

	Mean value g/L	CV %
Control specimen 1	0.57	3.58
Control specimen 2	1.45	1.79
Specimen 1	0.66	4.25
Specimen 2	1.20	3.42
Specimen 3	2.02	2.43

Reproducibility (total precision)

Reproducibility according to the recommendations found in the CLSI (NCCLS), EP5-A protocol (5) with samples tested in duplicate for 20 days (2 series per day):

- 2 controls
- 2 specimens (low / high levels)

	Mean value g/L	CV %
Control specimen 1	0.82	5.66
Control specimen 2	2.13	4.20
Specimen 1	0.87	7.13
Specimen 2	1.94	5.50

Measuring Range

The assay confirmed a measuring range from 0.07 g/L to 4.35 g/L.
The measuring range is extended up to 13.05 g/L with the automatic post-dilution.
The reagent linearity has been assessed up to 4.35 g/L according to the recommendations found in the CLSI (NCCLS), EP6-P protocol (6).

Correlation

Number of patient samples: 100
Specimens are correlated with a commercial reagent taken as reference according to the recommendations found in the CLSI (NCCLS), EP9-A2 protocol (7).
The equation for the allometric line obtained using Passing-Bablock regression procedure (8) is:
Y = 1.00 X + 0.04 (g/L)
with a correlation coefficient r^2 = 0.9629.

Interferences

Haemoglobin: No significant influence is observed up to 290 µmol/L (500 mg/dL).
Triglycerides: No significant influence is observed up to an Intralipid® concentration (representative of lipemia) of 7 mmol/L (612.5 mg/dL).

[d]Modification: general precautions modification.

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Total Bilirubin: No significant influence is observed up to 705.6 µmol/L (41.3 mg/dL).
Direct Bilirubin: No significant influence is observed up to 736 µmol/L (43.1 mg/dL).
Other limitations are given by Young as a list of drugs and preanalytical variables known to affect this methodology (9, 10).

Prozone Effect

No antigen excess has been detected up to a concentration of 15.7 g/L.

Calibration Stability

The reagent is calibrated on Day 0. The calibration stability is checked by testing 2 control specimens.
The calibration stability is 27 days.
Note: A recalibration is recommended when reagent lots change, and when quality control results fall outside the range established.

Reference

1. Thomas L. Clinical Laboratory Diagnostics. 1st ed. Frankfurt: THBooks Verlagsgesellschaft, (1998): 663-667.
2. Shahangian S, Agee KA and Dickinson RP. Concentration Dependencies of Imunoturbidimetric Dose-response Curves: Immunoturbidimetric Titer and Reactivity, and Relevance to Design of Turbidimetric Immunoassay. Clin. Chem. (1992) **38** (6): 831-840.
3. Vassault A, Grafmeyer D, Naudin C et al. Protocole de validation de techniques (document B). Ann. Biol. Clin. (1986) **44**: 686-745.
4. Council Directive (2000/54/EC). Official Journal of the European Communities. No. L262 from October 17, 2000: 21-45.
5. Evaluation of Precision Performance of Clinical Chemistry Devices. Approved Guideline, CLSI (NCCLS) document EP5-A (1999) **19** (2).
6. Evaluation of the Linearity of Quantitative Analytical Methods. Proposed Guideline, CLSI (NCCLS) document EP6-P (1986) **6** (18).
7. Method Comparison and Bias Estimation Using Patient Samples. Approved Guideline, 2nd ed., CLSI (NCCLS) document EP9-A2 (2002) **22** (19).
8. Passing H, Bablock W. A new biometrical procedure for testing the equality of measurements from two different analytical methods. J. Clin. Chem. Clin. Biochem. (1983) **21**: 709-20.
9. Young DS. Effects of Drugs on Clinical Laboratory Tests. 4th Edition, Washington, DC, AACC Press (1997) **3**: 143-163.
10. Young DS. Effects of Preanalytical Variables on Clinical Laboratory Tests. 2nd Edition, Washington, DC, AACC Press (1997) **3**: 120-132.