Rel Assay Diagnostics

Haptoglobin (HAPT) Assay Kit

Immunoturbidimetric Method — Product Insert

For in vitro diagnostic use only

Product Name

English Name: Kit For Haptoglobin Assay (Immunoturbidimetric Method)

Intended Use

For the quantitative determination of haptoglobin (HAPT) in human serum. For in vitro diagnostic use only.

Haptoglobin is synthesized by hepatocytes and functions as a hemoglobin-transporting and acute-phase protein. As a strong positive acute-phase reactant, haptoglobin increases during acute infection, inflammation, tissue necrosis, and trauma. Haptoglobin binds to hemoglobin, forming a stable Hp-Hb complex. This hemoglobin is derived from pathological hemolysis. These complexes are deposited in hepatocytes with a half-life of less than 10 minutes. After 3 days, hemoglobin is enzymatically metabolized and haptoglobin is released. The formation and rapid clearance of these complexes in circulation prevents hemoglobinuria and excessive iron loss from the kidneys.

Decreased haptoglobin is observed in chronic hepatitis, hemolytic diseases, and macrocytic anemia (megaloblastic anemia).

Test Principle

Haptoglobin in the sample reacts with the corresponding antibody (anti-haptoglobin antibody) in the liquid phase. Under sufficient antibody conditions, the antigen-antibody complex forms a measurable turbidity. The turbidity is proportional to the concentration of HAPT in the sample. By comparing the absorbance change with that of calibrators of known concentration, the HAPT content in the sample can be quantitatively determined.

Reaction: HAPT antigen + Anti-HAPT antibody → Antigen-antibody polymer

Main Components

Reagent 1 (R1):

Component	Concentration
Tris (Tris-hydroxymethyl aminomethane) buffer	50 mmol/L
Sodium azide	0.95 g/L

Reagent 2 (R2):

Component	Concentration
Anti-human haptoglobin antibody	As required
Sodium azide	0.95 g/L

Multi-Analyte Calibrator (Traceable to ERM-DA470k):

Component	Concentration
α2-Macroglobulin	See label
α1-Acidic glycoprotein	See label
α1-Antitrypsin	See label
Haptoglobin	See label
Transferrin (Protein matrix)	See label

- Note: Components from different lot numbers are not interchangeable.

Storage Conditions and Validity

- Sealed storage at 2–8 °C: stable for 18 months.
- After opening, store at 2–8 °C. R1 is stable for 30 days; R2 is stable for 30 days.
- Calibrator: store at –20 °C until the expiration date (18 months). Use immediately after thawing; do not save unused portions.
- Manufacturing date: see outer package.

Applicable Instruments

This reagent is suitable for use on the following automated biochemistry analyzers: Hitachi 7020/7060/7080/7170/7180/7600; Beckman (Olympus) AU480/640/680/2700/5411/5421/5431/5441/5811/5821/5831/5841; Beckman DXC800/CX/LX; Abbott Architect c8000/c16000; Roche Cobas c501/c502/c701/c702; Roche Modular P800; Siemens Dimension RxL/Xpand Plus; Siemens ADVIA 2400; Toshiba TBA-120FR/2000FR; and Mindray BS-800.

The multiparameter protein calibrator is suitable for use on the following automated biochemistry analyzers: Hitachi 7180, Beckman (Olympus) AU5811, Roche Cobas c502, and Siemens Dimension Xpand Plus.

Please request the specific application parameters for these automated biochemistry analyzers separately.

Sample Requirements

- Specimen: serum; hemolysis should be avoided.
- Storage at 2–8 °C: stable for up to 7 days.
- Pre-dilution: dilute sample with 0.9% NaCl at a ratio of 1 + 15 (sample : diluent).
- No interference from: bilirubin ≤ 60 mg/dL, triglycerides (fat emulsion) ≤ 750 mg/dL, or hemoglobin ≤ 1000 mg/dL.

Test Methods

- Liquid reagents are ready for use; no preparation required.

Testing conditions:

Parameter	Value
Reaction type	Two-point end method
Sample volume	10 µL
Temperature	37 °C
Reagent R1 volume	250 µL
Wavelength	340 nm
Reagent R2 volume	83 µL
Cuvette path length	1 cm

Operation steps: Sample 10 µL; R1 250 µL (first reading point, 3–5 minutes); R2 83 µL (second reading point, 300 seconds).

Calibration

- It is recommended to use PREB calibrator or other suitable calibrators for calibration.
- Calibration frequency: (1) after any change of reagent lot number; (2) as required by quality control needs.

Calculation

Calibration curve method: Plot the change in absorbance (A cal – A blank) of each calibrator dilution against its corresponding concentration to establish the calibration curve. Determine the HAPT content in the patient sample by locating the sample's (A sample – A blank) value on the calibration curve.

Quality Control

- It is recommended to use certified control materials to monitor the procedure.
- Each laboratory should establish its own quality control plan and take corrective actions when control results fall outside the acceptable range.

Reference Interval

0.3–2.0 g/L

- This reference value is derived from CRM 470 Protein Standardization. Each laboratory is advised to establish its own reference range.

Interpretation of Test Results

- If the sample concentration exceeds the linear range, dilute with physiological saline and re-test; multiply the result by the dilution factor.
- Clinical diagnosis should integrate clinical data with laboratory findings. Diagnosis should not be based on a single test result.

Limitations of Testing Methods

- The linear range, as validated per this insert, is up to 4.00 g/L.
- The linear range depends on the sample-to-reagent ratio and the specific analyzer used.
- Reducing the sample volume can extend the linear range but will simultaneously reduce analytical sensitivity.
- Stable and reproducible results cannot be obtained when the concentration is < 0.20 g/L.

Product Performance Indicators

- Appearance: R1: colorless transparent liquid; R2: colorless transparent liquid; Calibrator: colorless to pale yellow liquid.
- Linear range: 0.20–4.00 g/L. Coefficient of determination (R^2) ≥ 0.990. At ≥ 1.0 g/L, relative deviation B% ≤ 20%; at < 1.0 g/L, absolute deviation B ≤ 0.2 g/L.
- Precision: Within-run CV ≤ 8.0%; Between-run CV ≤ 10.0%.
- Blank absorbance: A (340 nm, 1 cm) ≤ 0.30.
- Analytical sensitivity: Absorbance difference (ΔA) for 1 g/L sample ≥ 0.025 Abs.
- Accuracy: Correlation coefficient r ≥ 0.975; relative deviation ≤ 15.0%.
- Calibrator accuracy: Using certified reference material (ERM-DA470K), relative deviation ≤ ±15%.
- Calibrator uniformity: Between-bottle CV ≤ 10.0%.

Precautions

- This product is for in vitro diagnostic use only; do not use it for any other purpose.
- Avoid contamination during use.
- Do not use reagents that have exceeded their stated expiration date.
- Reagents that show visible particles or turbidity are considered degraded and should be discontinued.
- Do NOT freeze. Freezing may permanently alter the analytical performance of the reagents.
- Handle all patient samples and waste materials according to relevant regulations.