Haptoglobin

Control Set for control of precision of the quantitative colorimetric test for Haptoglobin in serum or plasma

Cat. No: TP801-Con
Kit size: Level 1 control 1 x 1ml
Level 2 control 1 x 1ml

Intended Use:

The Haptoglobin control material is intended for use with the Tridelta Haptoglobin colorimetric kit (**Cat no: TP801**). It is strictly for in vitro veterinary use as an aid in monitoring day-to-day assay performance. Components of the control set are available as a kit only.

Quality Control Materials Provided & Reagent Description:

- Level 1: 1 x 1ml Haptoglobin control
- Level 2: 1 x 1ml Haptoglobin control

The Haptoglobin controls are derived from processed serum. Other additives are included to preserve the products characteristics.

Waste Management:
Please refer to local legal requirements.

Materials required but not provided:
Haptoglobin colorimetric kit (**Cat no: TP801**), automated analyser or microplate reader and its requirements for use, a vortex mixer, 200µl pipettes and disposable tips.

Reagent preparation and use:

Controls should be stored at 2-8^{0}C. The controls are ready to use and require no preparation. Ensure all controls are at room temperature for approximately thirty minutes prior to use to ensure temperature equilibration. Mix by inversion at least 5 times to ensure homogeneity prior to use.

Refer to the quality control procedure for instruction. Store any unused material at 2 - 8^{0}C. Prior to reuse, mix contents thoroughly.

Storage instructions and stability:

- **Unopened control at 2-8^{0}C:** Unopened controls are stable until the last day of the month of the expiration date printed on the outer box label.
- **Opened control at 2-8^{0}C:** Opened Haptoglobin controls are stable for 2 months if kept stoppered in their original containers and free from contamination or until the last day of the month of the expiration date printed on the outer box label whichever comes first.

Protect all reagents from extreme heat. In order to ensure maximum stability of the Haptoglobin controls on each automated chemistry analyzer, it is important to use proper boats and anti-evaporation tray covers.

Procedure & Sample Handling:

Assay the controls as unknowns, in the same manner as all serum samples, according to the procedures provided in the Haptoglobin colorimetric kit package insert, in the context of an internal quality control programme.
Once opened a 2-month expiry date should be recorded on the control vial.

Warnings and Precautions:

For in vitro veterinary use only. Do not use control material if solution is not clear. Follow universal precautions and handle all components as if capable of transmitting infectious agents.

Quality Control Procedure
The Haptoglobin test should be assessed using control material and kit calibrator. It is recommended these controls be tested as follows:

- **Included in every assay**
- If the **instrument** undergoes any **maintenance or cleaning**.

The level of performance is achieved when the analyte values obtained for each control are within the **"Acceptable Control Range"** as determined by each laboratory.

Expected values

Expected control values, **established using the Cobas Mira instrument**, are provided in table 1. However, laboratories should establish their own control range. The manufacturers stated ranges give an indication of where a customer's mean and ranges may be established, but the manufacturer data is not an appropriate substitute for a mean and QC limits determined from each laboratory's actual data.

Table 1:

Haptoglobin Control	Mean (mg/ml)	Range (mg/ml)
Level 1	0.35	0.222-0.47
Level 2	1.45	1.031-1.724

The laboratory should determine the performance of their measurement system and set an appropriate mean and QC limits for the control materials based on their own data. New lots of control material should be analyzed in parallel with the control material in current use.

Controls should be monitored and charted on a routine basis to analyze values and trends.

If control values fall outside the designated ranges and repetition of the assay excludes technical error, the following steps should be taken:

1. Check expiry date of kit.
2. Check reaction temperature.
3. Check cleanliness of glassware and pipettes.
4. Check wavelength setting and light source.
5. Check water, contaminants such as bacterial growth may contribute to inaccurate results.

Development and manufacturing of this assay is done by
Tridelta Development Limited,
Unit 7 Block F Maynooth Business Campus,
Maynooth,
Co. Kildare,
Ireland.

Contact Details
For further information or for technical assistance contact the company:

1. e-mail: general@trideltaltd.com
2. Phone 00353 1 6290635
3. Fax: 00353 1 6290687