



Intended purpose/Intended use

Eurotrol HemoLin is an assayed hemoglobin control intended for professional use in the verification of the linearity of the HemoCue® B-Hemoglobin and the HemoCue Hb 201 systems.

IVD Medical Device

Eurotrol HemoLin complies with the IVD Medical Device Directive 98/79/EC and carries the CE mark. Eurotrol HemoLin is for in vitro diagnostic use only.

Summary

Eurotrol HemoLin is a quality control material with a known hemoglobin concentration. Eurotrol HemoLin may be used in the verification of the linearity of the HemoCue B-Hemoglobin and the HemoCue Hb 201 systems. Please refer to local guidelines for recommended frequency of use.

Reagents

Eurotrol HemoLin is produced at five physiologically relevant levels. Each vial containing 1.0 mL of purified bovine hemolysate. Each box contains 1 dropper of each level.

Storage and stability

Eurotrol HemoLin should be stored unopened in the refrigerator at 2–8 °C (35–46 °F). Stored unopened at this temperature it is guaranteed stable as indicated until the expiration date on the outer box. After opening the vial, it is stable for 30 days when properly recapped and stored at 2–8 °C (35–46 °F) or at room temperature 15–30 °C (59–86 °F).

Procedures/instructions for use

1. Allow the vial to stand for 15 minutes at room temperature 15–30 °C (59–86 °F).
2. Gently mix the vial 8–10 times before sampling.
3. Do not fill the cuvette from the vial. Dispense a drop of the control material onto a hydrophobic surface, for example a plastic film. Fill the cuvette according to the manufacturer's instructions. Wait one minute before placing the cuvette in the instrument.
4. Wipe any excess material from the vial and the cap with a clean tissue. Recap the vial tightly.
5. If the control does not perform as expected, review the instructions for use of the instrument to see if the test was performed correctly. Check the expiration date and storage conditions for the control and the cuvettes. Repeat the test. If the control still does not perform as expected, contact technical assistance.

Precautions









1. For in vitro diagnostic use only.
2. Caution: Eurotrol HemoLin is an Animal Blood Product. Bovine based materials do not carry biohazards for man, such as Hepatitis B Surface Antigen (HBsAg), Hepatitis C Virus (HCV) and Human Immunodeficiency Virus (HIV-1/HIV-2). This product is free from TSE.
3. It is good laboratory practice to follow the same precautions as with patient samples when handling or disposing vials.
4. This product should not be disposed of in general waste. Consult local environmental authorities for proper disposal.
5. Eurotrol HemoLin is not to be used as a calibrator.

Expected results

The mean assay value provided on the vial label is derived from replicate analyses on factory calibrated HemoCue systems. The values are only valid on the HemoCue B-Hemoglobin and the HemoCue Hb 201 systems. Results obtained should fall within the expected range specified for the control.

Manufactured by Eurotrol B.V., The Netherlands

Symbols used

	Attention, see instructions for use		Batch code
	Use by		Temperature limitation
	In Vitro Diagnostic Medical Device		Reference number
	Manufacturer		CE Mark