

Intended purpose/Intended use

Eurotrol GlucoLin is an assayed glucose control intended for professional use in the verification of the linearity of the HemoCue® Glucose systems.

IVD Medical Device

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

Summary

Eurotrol GlucoLin is a quality control material with a known glucose concentration. Eurotrol GlucoLin may be used in the periodic verification of the precision and accuracy of the HemoCue Glucose systems. Please refer to local guidelines for recommended frequency of use.

Reagents

Eurotrol GlucoLin is produced at five physiologically relevant levels. Each vial contains 1.0 mL of purified bovine plasma with glucose.

Storage and stability

Eurotrol GlucoLin must be stored 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).

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. Place the cuvette in the analyzer for immediate analysis.
4. Wipe any excess material from the vial and the cap with a clean tissue. Recap the vial tightly.
5. Store in the refrigerator at 2–8 °C (35–46 °F).
6. 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 GlucoLin 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 of vials.
4. This product should not be disposed of in general waste. Consult local environmental authorities for proper disposal.
5. Eurotrol GlucoLin is not to be used as a calibrator.

Expected results

The mean assay values provided on the enclosed assay sheet are derived from replicate analyses on factory calibrated HemoCue Glucose systems. The values are only valid on the HemoCue Glucose systems as referred to in the assay sheet. Values for "HemoCue whole blood systems" are applicable for HemoCue Glucose systems reporting whole blood values. Values for "HemoCue plasma equivalent systems" are applicable for HemoCue Glucose systems reporting plasma equivalent values. Results obtained should fall within the expected range specified for the control. Not all HemoCue Glucose systems are available world wide.

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