Eurotrol
Your Global Reference Point for Quality Control

Glucotrol-AQ

(EN) Eurotrol Glucotrol-AQ

Intended purpose/Intended use
Eurotrol GlucoTrol-AQ is an assayed glucose control intended for professional use in the verification of the precision and accuracy of the HemoCue Glucose 201 analyzer.

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

Reagents
Eurotrol GlucoTrol-AQ is available at two physiologically relevant levels: Low (1) and High (3). Each vial contains 2.0 mL of an aqueous buffered glucose solution.

Summary
Eurotrol GlucoTrol-AQ is a quality control material with a known glucose concentration. Eurotrol GlucoTrol-AQ 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.

Storage and stability
Eurotrol GlucoTrol-AQ 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 and the vial. After opening the vial, GlucoTrol-AQ is stable for 1 month when properly closed and stored at 2–30 °C (35–86 °F).

Procedures
1. Allow the vial to stand for 15 minutes at room temperature 15–30 °C (59–86 °F).
2. Gently mix the vial by inverting 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 the vial at 2–30 °C (35–86 °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. This product should not be disposed of in general waste. Consult local environmental authorities for proper disposal.
3. Eurotrol GlucoTrol-AQ is not to be used as a calibrator.

Expected results
The mean assay value provided on the enclosed assay sheet is derived from replicate analyses on factory calibrated HemoCue Glucose 201 analyzers. 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.

For further information or technical assistance, please contact Eurotrol Inc.:
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Symbols used

Caution	Batch code
Use-by date	Temperature limit
In Vitro Diagnostic Medical Device	Catalogue number
Manufacturer	CE Mark

Valuesheet

Box Batch Number LOT **18050008**

2020-11		Low (Level 1) LOT 84837		High (Level 3) LOT 84839	
HemoCue Glucose analyzers		**Mean**	**Range**	**Mean**	**Range**
Glucose 201 analyzer*	mmol/L	3.8	2.7 - 4.9	17.6	15.0 - 20.2
	mg/dL	69	50 - 88	317	271 - 363

*plasma glucose equivalent values

Low (1) Glucose 201 systems

0 2 0 3 8 2 8 4 8 3 7 0 6 9 0 5 0 0 8 8

High (3) Glucose 201 systems

2 2 0 3 8 2 8 4 8 3 9 3 1 7 2 7 1 3 6 3