Eurotrol
Your Global Reference Point for Quality Control

(GB) Eurotrol Hypoxic QC

Intended purpose
Eurotrol Hypoxic QC is a pre-tonometered *bovine oxyhemoglobin (O_2Hb)* quality control material for professional use in the performance assessment of the critical low pO_2 value range of the Abbott® i-STAT® analyzer. This quality control material is used to check instrument calibration, operating temperature and other performance related characteristics.

IVD Medical Device
Eurotrol Hypoxic QC complies with the European Directive 98/79/EC on in vitro diagnostic medical devices and carries the CE mark.
Eurotrol Hypoxic QC complies with the following US codes of Federal Regulations (CFR): 42 CFR part 72 and 21 CFR parts 606, 640 and 820.
Eurotrol Hypoxic QC is for in vitro diagnostic use only.

Summary
Eurotrol Hypoxic QC is available at one level with a known pO_2-value in the critical low pO_2 value range. It is intended that Eurotrol Hypoxic QC should be used in the periodic verification of the precision and accuracy of the Abbott i-STAT analyzer.

Reagents
Eurotrol Hypoxic QC provides one level in the critical low pO_2 value range, each ampule holding 3 mL of solution. Eurotrol Hypoxic QC is prepared from a stroma-free bovine hemoglobin solution and provides the oxygen buffering characteristics of fresh whole blood. The concentrations of total hemoglobin and acid-base levels are within the normal physiological range. Tonometry with a predetermined level of oxygen balanced with nitrogen provides a distinct assay value for partial pressure of oxygen measurements. Eurotrol Hypoxic QC contains no preservatives, viscosity adjusters or other additives that might adversely effect electrode measurements.

Storage and stability
Eurotrol Hypoxic QC should be stored between 2–8 °C (35–46 °F) in the dark. Stored unopened at this temperature it is guaranteed stable until the expiration date as indicated on the outer box. After opening an ampule of Eurotrol Hypoxic QC, it should be used within 10 minutes.

Directions for use
1. Remove ampule from box and foam insert. Equilibrate the ampule at room temperature for a minimum of 1 hour, but not more than 8 hours. **Note**: Do not put ampules back into refrigerator once exposed to room temperature.
2. Immediately before use, shake the ampule vigorously for at least fifteen seconds to re-equilibrate the gases with the solution.
3. Swirl the ampule gently to return liquid to the bottom. Allow bubbles to rise to the surface before opening the ampule.
4. Protect fingers with gauze, tissue or gloves and carefully snap off the neck of the ampule. The QC material should be anaylzed within 10 minutes after opening the ampule. Follow the sampling procedure according to instrument operating instructions.
5. Please refer to local guidelines for recommended frequency of use.

Precautions
1. For in vitro diagnostic use only.
2. Caution: Animal Blood Product. Bovine based materials do not carry biohazards for man, such as HepB, HepC and HIV. This product is free of TSE.
3. These products should not be disposed of in general waste. Consult local environmental authorities for proper disposal.
4. Eurotrol Hypoxic QC is not to be used as a calibrator.

Assigned values
Enclosed *p*O2 values have been obtained by equilibrating randomly selected ampules from the applicable batch at 25 ± 1°C before measurement and have been measured on multiple instruments using multiple types of cartridges.
The values of the Eurotrol Hypoxic QC for the Abbott i-STAT analyzer are assigned by Abbott Point of Care.

Please Note
- Incorrect sampling, storage, etc. may cause the readings to deviate from the target values.
- The pO_2 values of Eurotrol Hypoxic QC vary inversely with temperature changes. For each °C change in temperature between 18 and 26 °C, the pO_2 changes ±1.5%. To obtain a high degree of correlation with the values in the table, the ampules should be equilibrated as close to 25 °C as possible.
- Eurotrol Hypoxic QC is sensitive to most of the instrument related factors that can cause unexpected analytical deviations.
- Incorrect sampling, storage, etc. may cause the readings to deviate from the target values.

This product has been manufactured according to Eurotrol specifications.

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Symbols used

	Attention, see instructions for use	LOT	Batch code
	Use by	2°C 8°C	Temperature limitation
IVD	In Vitro Diagnostic Medical Device	REF	Reference number
	Manufacturer	CE	CE mark

References
1. Burnett RW, Covington AK, Maas AHJ, Müller-Plathe O, Weisberg HF, Wimberley PD, Zijlstra WG, Siggaard-Andersen O, and Durst RA, IFCC Method (1988) for tonometry of blood: Reference materials for pCO_2 and pO_2, J. Clin. Chem. Clin. Biochem. 1989;27: 403-408, Ann. Biol. Clin. 1989;47: 373-376, Clinica Chimica Acta 1989;185: S17-S24, Biochimica Clinica 1989;13: 945-949. JIFCC 1989;1: 78-81, J. Biomed. Lab.Sci. 1989;2: 185-192.
2. Maas AHJ, Weisberg HF, Burnett RW, Müller-Plathe O, Wimberley PD, Zijlstra WG, Durst RA, and Siggaard-Andersen, Approved IFCC Methods. Reference method (1986) for pH measurement in blood, J. Clin. Chem. Clin. Biochem. 1987;25: 282-289. Clinica Chimica Acta 1987;165: 97-109, Labmedica 1986/1987;3: 33-37, Biochimica Clinica 1988;12: 241-249.

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