

GB Eurotrol GAS-ISE-Hct QC

Intended Purpose

Eurotrol GAS-ISE-Hct QC is an assayed aqueous quality control material applicable for the Abbott i-STAT® POCT analyzer. It is intended that Eurotrol GAS-ISE-Hct QC should be used in the periodic verification of the precision and accuracy of the Abbott i-STAT POCT analyzer when measuring: pH, pO₂, pCO₂, Hct, cNa⁺, cK⁺, cCa²⁺, cCl⁻, cGlu, cLac, Urea, Creatinine and TCO₂.

IVD Medical Device

Eurotrol GAS-ISE-Hct QC complies with the European Directive 98/79/EC on in vitro diagnostic medical devices and carries the CE mark.

Eurotrol GAS-ISE-Hct QC complies with the following US codes of Federal Regulations (CFR): 42 CFR part 72 and 21 CFR parts 606, 640 and 820.

Eurotrol GAS-ISE-Hct QC is for in vitro diagnostic use only.

Summary

Eurotrol GAS-ISE-Hct QC quality control material is a three (3) level product, containing twelve (12) ampules of one (1) level in each box. Each level Eurotrol GAS-ISE-Hct QC contains known values of blood gases, electrolytes and metabolites. It is intended that Eurotrol GAS-ISE-Hct QC should be used in the periodic verification of the precision and accuracy of the Abbott i-STAT POCT analyzer when measuring: pH, pO₂, pCO₂, Hct, cNa⁺, cK⁺, cCa²⁺, cCl⁻, cGlu, cLac, Urea, Creatinine and TCO₂.

Reagents

Eurotrol GAS-ISE-Hct QC provides three (3) physiological relevant levels, each ampule holding 2.5 mL solution. Eurotrol GAS-ISE-Hct QC quality controls are prepared using salts in an aqueous physiologically buffered matrix. Tonometry with predetermined levels of oxygen and carbon dioxide balanced with nitrogen and different salt concentrations provides three (3) distinct levels for each parameter, simulating clinically significant ranges of acid-base and electrolyte balance, respiratory function, glucose, lactate, Urea and Creatinine concentrations, covering the reportable range of the Abbott i-STAT POCT analyzer.

Storage and stability

Eurotrol GAS-ISE-Hct QC must be stored at a temperature of 2–8 °C (35–46 °F). Stored unopened at this temperature it is guaranteed stable as indicated until the expiration date on the ampule and on the outer box. After opening the Eurotrol GAS-ISE-Hct QC ampule it is stable for 30 seconds.

Procedures

1. Allow the ampule to adapt to a temperature of 25 ± 1 °C (77 ± 2°F).
2. Immediately before use, shake the ampule vigorously for at least fifteen seconds to re-equilibrate the gases with the solution. When shaking, the ampule should be held between thumb and index finger.
3. Swirl the ampule gently to return the solution to the bottom of the ampule. Allow bubbles to rise between shaking and before opening the ampule.
4. Protect fingers with gauze, tissue or gloves.
5. **Hold ampule with the coloured dot upside. Snap off the neck of the ampule in the opposite direction of the coloured dot.**
6. Transfer the sample from the ampule into a syringe **within 30 seconds after opening of the ampule**. Gently load the sample from the syringe into the test cartridge according to the instructions for analyses of patient samples of the Abbott i-STAT POCT analyzer.
7. Please refer to local guidelines for recommended frequency of use.

Precautions

1. Eurotrol GAS-ISE-Hct QC is for use on the Abbott i-STAT analyzer only.
2. For in vitro diagnostic use only.
3. Eurotrol GAS-ISE-Hct QC is not to be used as a calibrator.

4. These products should not be disposed of in general waste. Consult local environmental authorities for proper disposal.

Reference values

Enclosed values have been obtained by equilibrating randomly selected ampules from the applicable batch at 25 ± 1°C before measurement. The values have been obtained on multiple i-STAT instruments using multiple cartridge types.


Enclosed values are applicable for all relevant cartridges types and cartridge lots.

The value ranges are mean values for each parameter ±3SD within which the obtained results must fall.

Please Note









- The values in the table are applicable only to the assigned lot number and at sea level.
- Incorrect or inaccurate sampling, storage, etc. may cause the readings to deviate from the target values.
- The pO₂-values of Eurotrol GAS-ISE-Hct QC vary inversely with temperature changes. For each °C change in temperatures between 18 and 26 °C, the pO₂-values may change up to 1,5%.
- Eurotrol GAS-ISE-Hct QC is sensitive to most of the instrument related factors that can cause unexpected analytical deviations.
- Eurotrol GAS-ISE-Hct QC controls do not contain protein and therefore may not detect malfunctions sensitive to these components.
- Eurotrol GAS-ISE-Hct QC is very sensitive to room air contamination. This is caused by the low solubility of oxygen in aqueous solutions which results in low buffering capacity. 60 seconds after opening the ampule, the control material may show deviation for pO₂ of up to 5%. Compared to oxygen, the solubility of carbon dioxide in aqueous solution is much higher and the concentration of carbon dioxide in room air is much lower. The error is less than 2% over the entire range in all eleven levels (15–100 mmHg). The effect of room air on pH is negligible.

This product has been manufactured according to Eurotrol specifications.

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Symbols used

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

i-STAT is a registered trademark of Abbott Laboratories