

Intended Purpose

Eurotrol GAS-ISE Hct LVM is an assayed aqueous blood gas, electrolyte and metabolite control material suitable for calibration verification of the Abbott i-STAT® POCT analyzer.

It is intended that Eurotrol GAS-ISE Hct LVM should be used in the periodic verification of the precision, accuracy and linearity of the Abbott i-STAT POCT analyzer when measuring: pH, pO_2 , pCO_2 , Na^+ , K^+ , Ca^{++} , Cl⁻, Glucose, Lactate, Urea, Creatinine, TCO₂ and Hematocrit.

IVD Medical Device

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

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

Summary

Eurotrol GAS-ISE Hct LVM quality control material is a five (5) level product, containing one (1) ampule per level. Each level of Eurotrol GAS-ISE Hct LVM contains known values of blood gases, electrolytes and metabolites.

Reagents

Eurotrol GAS-ISE Hct LVM provides five (5) physiological relevant levels, each ampule holding 2.5 mL of solution. Eurotrol GAS-ISE Hct LVM 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 five (5) distinct levels for each parameter, simulating clinically significant ranges of acid-base and electrolyte balance, respiratory function, glucose, lactate, urea and creatinine concentrations, within the reportable range of the Abbott i-STAT POCT analyzer.

Storage and stability

Eurotrol GAS-ISE Hct LVM 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 LVM ampule, the product is stable for 30 seconds.

Procedures

- Remove the ampule from box and foam insert and equilibrate the ampule at room temperature (20–25°C/68–77°F) 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.
- Immediately before use, shake the ampule vigorously for at least fifteen seconds to re-equilibrate the gases with the solution by holding the ampule between the thumb and index finger.
- Swirl the ampule gently to return the solution to the bottom of the ampule. Allow any bubbles to rise before opening the ampule.
- Protect fingers with gauze, tissue or gloves.
- Hold ampule with the colored dot facing up. Snap off the neck of the ampule in the opposite direction of the colored dot. Please read the OPC-instruction leaflet for more details.**
- Using one of the techniques described under “Instructions for Blood Gas/Electrolyte/Metabolite Cartridges” in the Quality Control section of the i-STAT system manual, transfer sample from the ampule to the test cartridges within 30 seconds after opening the ampule.
Important: Use the Calibration Verification (CalVer) pathway from the Quality Tests Menu.
- Refer to CLIA regulations, state regulations, accrediting agency requirements as well as the i-STAT system manual for frequency of use

Precautions

- Eurotrol GAS-ISE Hct LVM is for use on the Abbott i-STAT analyzer only.

- For in vitro diagnostic use only.

- 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 (77 ± 2°F) before measurement. The values have been obtained on multiple i-STAT instruments using multiple cartridge types.

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 at sea level for the Abbot iSTAT POCT analyzer with the applicable cartridge types and cartridge lots only.
- Incorrect sampling, storage, or other mishandling may cause the readings to deviate from the target values.
- The pO_2 values of Eurotrol GAS-ISE Hct LVM controls vary inversely with temperature changes. For each °C change in temperatures between 18 °C and 26 °C (between 64.5 °F and 79 °F), the pO_2 changes 1.5% in the low level, 1.1% in the normal and 0.5% in the high level. To obtain a high degree of correlation with the values in the table, the ampules should be equilibrated as close to 25°C (71.6°F) as possible.
- Eurotrol GAS-ISE Hct LVM is sensitive to most of the instrument related factors that can cause unexpected analytical deviations.
- Eurotrol GAS-ISE Hct LVM controls are very sensitive to room air contamination. When sampling the fluid within 30 seconds, the error is less than 2% over the entire range in all levels*. The effect of room air on pH is negligible.

*Numbers are based on open ampule testing.

This product has been manufactured according to Eurotrol specifications.



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Symbols used



Attention, see instructions for use



Use by



In Vitro Diagnostic Medical Device



Manufacturer



Batch code



Temperature limitation



Reference number



CE mark

i-STAT is a registered trademark of Abbott Laboratories