

Intended Purpose

Eurotrol Hyperbaric QC is an assayed, pre-tonometered quality control material for professional use in the verification of the precision and accuracy of the critical high 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 Hyperbaric QC complies with the IVD Medical Device Directive 98/79/EC and carries the CE mark.

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

Eurotrol Hyperbaric QC is for in vitro diagnostic use only.

Summary

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

Reagents

Eurotrol Hyperbaric QC provides one level in the critical high pO_2 value range, each ampule holding 3 mL of solution. Eurotrol Hyperbaric QC is prepared using pure salts in a physiologically buffered aqueous solution. Tonometry with a predetermined level of oxygen balanced with nitrogen and different salt concentrations provides the distinct assay value for measurement of partial pressure of oxygen. Eurotrol Hyperbaric QC contains no preservatives, viscosity adjusters or other additives that might adversely effect electrode measurements.

Storage and stability

Eurotrol Hyperbaric QC can be stored at a temperature of 15–30 °C (59–86 °F). Stored unopened at this temperature it is stable as indicated until the expiration date on the ampules and the outer box. After opening an ampule of Eurotrol Hyperbaric QC, it is stable for 30 seconds.

Procedures

1. Prior to use, ampules should be brought to room temperature and/or incubated for 30 minutes in a water bath to assure proper temperature equilibration. To obtain a high degree of correlation with the values as shown in the table of the Value Assignment chart, the ampules should be equilibrated as close as possible to the associated temperature.
2. Immediately before use, shake the ampule vigorously for at least fifteen seconds to re-equilibrate the gases with the solution. When shaken, the ampule should be held between the 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 the ampule with the colored dot upside. Snap off the neck of the ampule in the opposite direction of the colored 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. 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 Hyperbaric QC is not to be used as a calibrator.

Assigned values

The assigned values have been obtained after equilibration of randomly selected ampules from the applicable batch at $25 \pm 1^\circ\text{C}$ before measurement and have been measured on multiple i-STAT analyzers using multiple types of cartridges.

The pO_2 of Eurotrol Hyperbaric QC varies inversely with the sample temperature. The expected pO_2 value for your applicable incubation temperature is shown in the table of the Value Assignment chart.

The values of the Eurotrol Hyperbaric QC for the Abbott i-STAT analyzer are assigned by Abbott Point of Care.

Please Note

- The values in the table are applicable only to the assigned lot number and at sea level.
- Incorrect sampling, storage, etc. may cause the readings to deviate from the target values.
- The pO_2 values of Eurotrol Hyperbaric QC vary inversely with temperature changes. Please consult the Value Assignment chart for the expected pO_2 value for your applicable temperature.
- Eurotrol Hyperbaric QC is sensitive to most of the instrument related factors that can cause unexpected analytical deviations. Eurotrol Hyperbaric QC does not contain protein and therefore may not detect malfunctions sensitive to these components.

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