

EN CueSee® VeriSTAT QC - Level 2

Intended Use

CueSee® VeriSTAT QC - Level 2 is an assayed aqueous quality control material for professional use in the verification of the precision and accuracy of the Abbott i-STAT® POCT analyzer.

It is intended that CueSee® VeriSTAT QC - Level 2 should be used in the periodic verification of the precision, accuracy of the Abbott i-STAT POCT analyzer when measuring: pH, pO₂, pCO₂, Na⁺, K⁺, Ca⁺⁺, Cl⁻, Glucose, Lactate, Urea, Creatinine, TCO₂ and Hematocrit.

IVD Medical Device

CueSee® VeriSTAT QC - Level 2 complies with the European Directive 98/79/EC on in vitro diagnostic medical devices and carries the CE mark.

CueSee® VeriSTAT QC - Level 2 complies with the following US codes of Federal Regulations (CFR): 42 CFR part 72 and 21 CFR parts 606, 640 and 820.

CueSee® VeriSTAT QC - Level 2 is for professional in vitro diagnostic use only.

Summary

CueSee® VeriSTAT QC - Level 2 is an assayed aqueous quality control material for professional use in the verification of the precision and accuracy of the Abbott i-STAT® POCT analyzer. Each ampule contains 2.5 mL of solution.

Reagents

CueSee® VeriSTAT QC - Level 2 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 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

CueSee® VeriSTAT QC - Level 2 must be stored at a temperature of 2-8 °C (35-46 °F). Stored unopened at this temperature it is guaranteed stable until the expiration date as indicated on the ampule and on the outer box. After opening the CueSee® VeriSTAT QC - Level 2 ampule, the product is stable for 30 seconds.

Procedures

1. Take the ampule out of its packaging and equilibrate the ampule to room temperature (20-25 °C/68-77 °F) for a minimum of 1 hour, but not more than 10 days. 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 by holding the ampule between the thumb and index finger.
3. Swirl the ampule gently to return the solution to the bottom of the ampule. Allow any bubbles to rise before opening the ampule.
4. Protect fingers with gauze, tissue or gloves.
5. **The One Point Cut (OPC) ampule must be opened as presented below.**
6. 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 of opening the ampule.
7. Refer to CLIA regulations, state regulations, accrediting agency requirements as well as the i-STAT system manual for frequency of use.

Precautions

1. CueSee® VeriSTAT QC - Level 2 is for use on the Abbott i-STAT analyzer only.
2. For in vitro diagnostic use only.
4. CueSee® VeriSTAT QC - Level 2 is not to be used as a calibrator.
3. 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 indicate the values for each parameter within which the obtained results must fall.

Please Note

- The values in the table are applicable at sea level for the Abbott i-STAT POCT analyzer with the applicable cartridge types and cartridge lots only.
- Due to variations in CLEW updates, cartridge type and cartridge lot number, for some analyte concentrations in CueSee® VeriSTAT QC - Level 2, results may fall outside of the i-STAT reportable range. If necessary, it is recommended that the Calibration Verification pathway be used to obtain a numerical result.
- Incorrect sampling, storage, or other mishandling may cause the readings to deviate from the target values.
- The pO₂ values of CueSee® VeriSTAT QC - Level 2 controls vary inversely with temperature changes. To obtain a high degree of correlation with the values in the table, the ampules should be equilibrated as close to 25 °C (77 °F) as possible.
- CueSee® VeriSTAT QC - Level 2 controls are very sensitive to room air contamination. To minimize the effect of air contamination, sample within 30 seconds of opening. The effect of room air on pH is negligible.

This product has been manufactured according to Eurotrol specifications.

For further information please contact:

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

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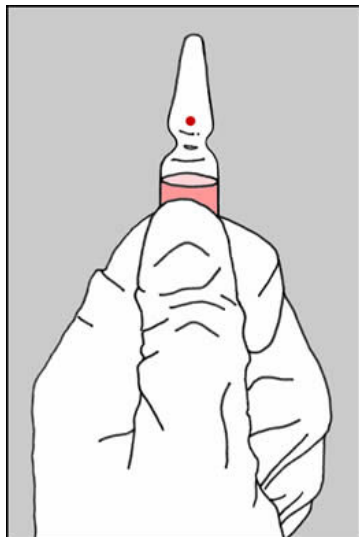
Eurotrol B.V., Keplerlaan 20, 6716 BS Ede, The Netherlands

Symbols used

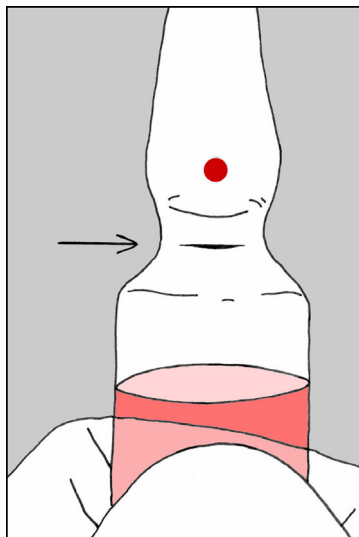
-  Attention, see instructions for use
-  Use by
-  In Vitro Diagnostic Medical Device
-  Manufacturer

-  Batch code
-  Temperature limitation
-  Reference number
-  CE mark

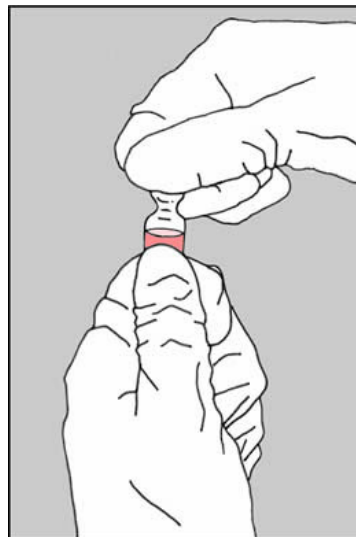
i-STAT is a registered trademark of Abbott Laboratories



Hold the bottom of the ampule with thumb pointing to the red colored dot.



Cut located below the red dot is the breaking point of the ampule.



Grasp the top of the ampule with other hand, positioning thumb at the red dot.



Press back to break at the cut under the red dot.