Eurotrol
Your Global Reference Point for Quality Control

EN CueSee® VeriSTAT LVM

Intended Purpose
CueSee® VeriSTAT 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 CueSee® VeriSTAT LVM should be used in the periodic verification of the precision and 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 LVM complies with the European Directive 98/79/EC on in vitro diagnostic medical devices and carries the CE mark.
CueSee® VeriSTAT LVM complies with the following US codes of Federal Regulations (CFR): 42 CFR part 72 and 21 CFR parts 606, 640 and 820.
CueSee® VeriSTAT LVM is for professional in vitro diagnostic use only.

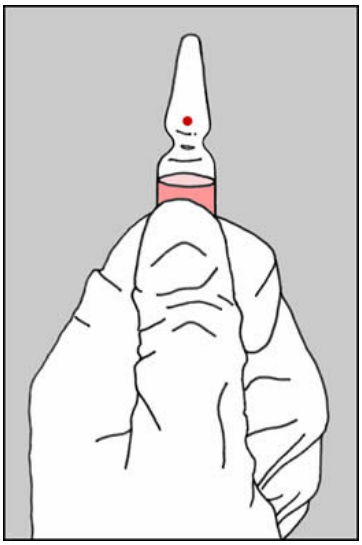
Summary
CueSee® VeriSTAT LVM quality control material is a five (5) level product, containing one (1) ampule per level. Each level of CueSee® VeriSTAT LVM contains known values of blood gases, electrolytes and metabolites.

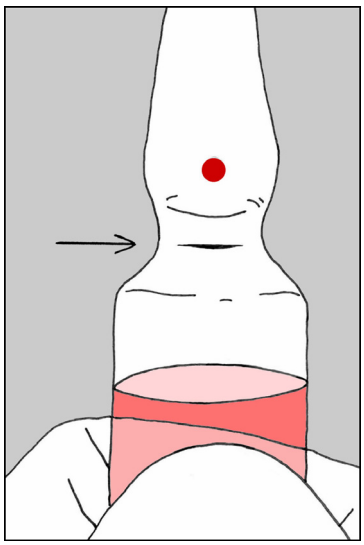
Reagents
CueSee® VeriSTAT LVM provides five (5) physiological relevant levels, each ampule containing 2.5 mL of solution. CueSee® VeriSTAT LVM quality controls are prepared using salts in an aqueous, physiologically buffered matrix. Tonometry with predetermined levels of oxygen and carbon dioxide balanced 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.

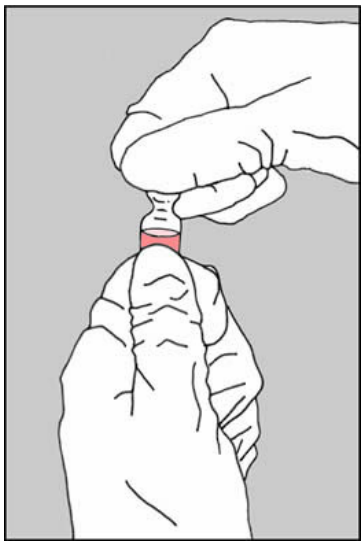
Storage and stability
CueSee® VeriSTAT LVM must be stored at a temperature of 2–8 °C (35–46 °F). Stored unopened at this temperature it is guaranteed stable until the expiration date as indicated on the ampule and on the outer box. After opening the CueSee® VeriSTAT LVM ampule, the product is stable 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:


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.

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.
   Important: Use the Calibration Verification (CalVer) pathway from the Quality Tests Menu.
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 LVM is for use on the Abbott i-STAT analyzer only.
2. For in vitro diagnostic use only.
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.
- Incorrect sampling, storage, or other mishandling may cause the readings to deviate from the target values.
- The pO2 values of CueSee® VeriSTAT LVM 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 LVM 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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Symbols used

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