

EN CueSee® Hyperbaric

Intended Purpose

CueSee® Hyperbaric is an assayed, quality control material for professional use in the verification of the precision and accuracy of the critically high pO₂ value range of many blood gas analyzers.

IVD Medical Device

CueSee® Hyperbaric complies with the IVD Medical Device Directive 98/79/EC and carries the CE mark. CueSee® Hyperbaric complies with the following US codes of Federal Regulations (CFR): 42 CFR part 72 and 21 CFR parts 606, 640 and 820. CueSee® Hyperbaric is for professional in vitro diagnostic use only.

Summary

CueSee® Hyperbaric is available at one level with a known pO₂ value in the critically high pO₂ value range. It is intended that CueSee® Hyperbaric should be used in the periodic verification of the precision and accuracy of blood gas analyzers.

Reagents

CueSee® Hyperbaric provides one level in the critically high pO₂ value range, each ampule holding 3 mL of solution. CueSee® Hyperbaric 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. CueSee® Hyperbaric contains no preservatives, viscosity adjusters or other additives that might adversely effect electrode measurements.

Storage and stability

CueSee® Hyperbaric should be stored at a temperature of 2–30 °C (36–86 °F). Stored unopened at this temperature the product is stable as indicated until the expiration date on the ampules and the outer box. After opening an ampule of CueSee® Hyperbaric, the product is stable for 30 seconds.

Procedures

1. Remove the ampule from box and tray. Equilibrate the ampule for a minimum of 1 hour to the room temperature where the testing will take place. Note the current room temperature.
2. Immediately before use, placing the ampule between the thumb and index finger, shake the ampule vigorously for at least fifteen seconds to re-equilibrate the gases with the solution.
3. Swirl the ampule gently to return liquid to the bottom. Allow bubbles to rise to the surface before opening the ampule.
4. Protect fingers with gauze, tissue or gloves.
5. **The One Point Cut (OPC) ampule must be opened as illustrated below.**
6. Using techniques described in the instrument manufacturer's system manual, transfer the sample from the ampule to the card, cartridge or analyzer within 30 seconds after opening of the ampule. Gently load the sample from the syringe to test cartridge/card following the sampling procedure of the instrument operating instructions.
Important: Use of the Quality Control or Calibration Verification Mode, depending on instrument manufacturer, may be needed to obtain high pO₂ results.
7. **For i-STAT instruments, read the pO₂ target range from the Eurotrol Value Assignment Sheet according to the corresponding room temperature. For epoc® System users, refer to assigned values at www.epocal.com.**
8. Refer to CLIA regulations, state regulations, accrediting agency requirements, or instrument system manual for 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. CueSee® Hyperbaric is not to be used as a calibrator.

Assigned Values

The pO₂ of CueSee® Hyperbaric varies inversely with the sample temperature. The Eurotrol assigned values for the i-STAT analyzer have been obtained after equilibration of randomly selected ampules from the applicable batch at 25 ± 1 °C before measurement and have been measured on multiple i-STAT analyzers using multiple types of cartridges. The expected pO₂ value for your applicable incubation temperature is shown in the table of the Value Assignment chart.

The assigned values for the epoc System have been obtained after equilibration of randomly selected ampules from the applicable batch at 22 ± 1 °C before measurement and have been measured on multiple epoc readers using multiple lots of cards. The assigned values can be found at www.epocal.com. Refer to the epoc System Manual for more information on target adjustments for variable ambient temperature and barometric pressure.

Please Note

- Incorrect sampling, storage, or other mishandling may cause the readings to deviate from the target values.
- The pO₂ values of CueSee® Hyperbaric 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 pO₂ changes 0.5%.
- The values in the table for the Abbott i-STAT are applicable at sea level and with the applicable cartridge types and cartridge lots only.
- For i-STAT users, 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.
- For epoc System users, to obtain a high degree of correlation with the values in the table, the ampules should be equilibrated as close to 22 °C (71.6 °F) as possible. Refer to the epoc System Manual for more information.
- CueSee® Hyperbaric is very sensitive to room air contamination. When sampling the fluid within 30 seconds, the error is less than 2%, 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

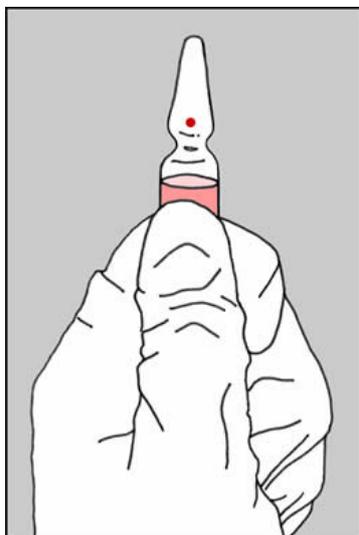
 Reference number

 CE mark

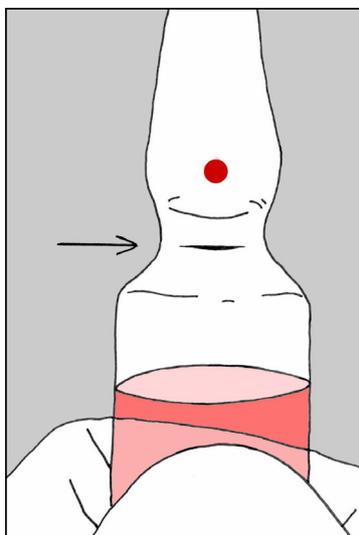
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i-STAT is a registered trademark of Abbott Laboratories.

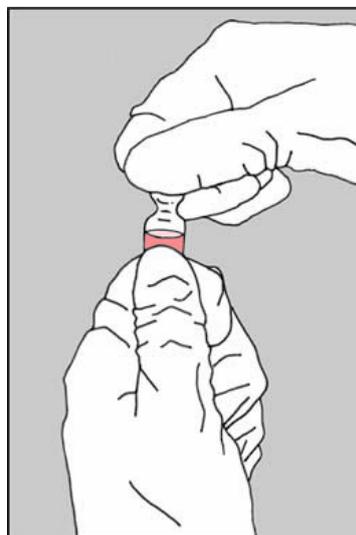
5. The One Point Cut (OPC) ampule must be opened as presented below:



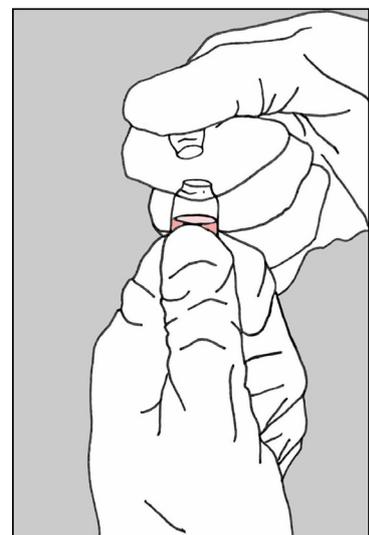
Hold the bottom of the ampule with thumb pointing to the red colored dot.



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.