

EN CueSee® Hypoxic

Intended Use

CueSee® Hypoxic is a pre-tonometered bovine hemoglobin (Hb) quality control material for professional use for monitoring blood gas analyzers' performance of Oxygen partial pressure (pO₂).

Test Summary

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

Contents

CueSee® Hypoxic provides one level in the critically low pO₂ value range, each ampule holding 2.5 mL of solution. CueSee® Hypoxic is prepared from a stroma-free bovine hemoglobin solution and provides the oxygen buffering characteristics of fresh whole blood. The concentrations of total hemoglobin and acid-base levels are within the normal physiological range. Tonometry with a predetermined level of oxygen balanced with nitrogen provides a distinct assay value for partial pressure of oxygen measurements. CueSee® Hypoxic contains no preservatives, viscosity adjusters or other additives that might adversely affect electrode measurements.

Storage and Stability

CueSee® Hypoxic should be stored between 2-8 °C (35-46 °F) in the dark. Stored unopened at this temperature it is guaranteed stable until the expiration date as indicated on the outer box. After opening an ampule of CueSee® Hypoxic, it should be used within 10 minutes.

Procedure

1. Remove ampule from box. Equilibrate the ampule at room temperature 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.
2. Immediately before use, 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 bottom. Allow bubbles to rise to the surface before opening the ampule.
4. Protect fingers with an ampule snapper, gauze, tissue or gloves and carefully snap of the neck of the ampule following the illustration below. The QC material should be analyzed within 10 minutes after opening the ampule. Follow the sampling procedure according to analyzer operating instructions.
5. Please refer to local guidelines for recommended frequency of use.

Warnings and Precautions

1. For in vitro diagnostic use only.
2. Caution: Animal blood product. Bovine based materials do not carry biohazards for man, such as HepB, HepC and HIV. This product is free of TSE.
3. These products should not be disposed of in general waste. Consult local environmental authorities for proper disposal.
4. CueSee® Hypoxic is not to be used as a calibrator.

Expected Values

Assigned values are established using the following measuring systems: Radiometer ABL835 FLEX blood gas analyzer, Abbott iSTAT® CG4+ system and epoc® Blood Analysis System. For this purpose, randomly selected ampules from the applicable batch of CueSee® Hypoxic have been equilibrated at 25 ± 1°C before measurement. Assigned values are available from <http://www.eurotrol.com/documents>, a paper version can be requested via the contact information shown below.

Limitations

- Incorrect handling, storage or sampling may cause the readings to deviate from the target values.
- The pO₂ values of CueSee® Hypoxic vary inversely with temperature changes. For each °C change in temperature between 18 and 26 °C, the pO₂ changes ±1.5%. To obtain a high degree of correlation with the values in the value sheet, the ampules should be equilibrated as close to 25 °C as possible.
- CueSee® Hypoxic is sensitive to most of the instrument related factors that can cause unexpected analytical deviations.

For further information and/or technical assistance, please contact:

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Symbols used

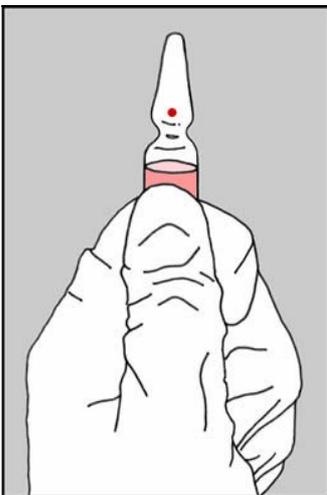


Caution
Use-by date
In vitro Diagnostic Medical Device
Manufacturer

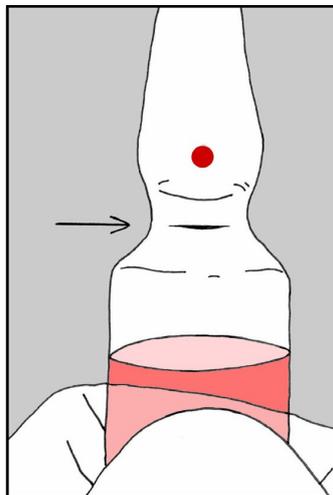


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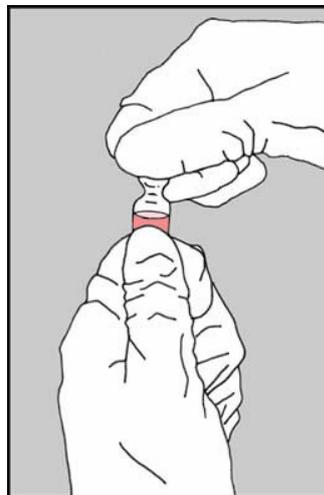
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Hold the bottom of the ampule with thumb pointing to the red colored dot.



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.