



pO₂ Accuracy EQA

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INTENDED USE

Weqas pO_2 Accuracy EQA samples are for in-vitro diagnostic use as an external quality assessment material. The material is used as an accuracy assessment for pO_2 analysis. The aim of the pO_2 study is to address some of the concerns regarding the matrix effects of aqueous material and to provide an accurate assessment of pO_2 .

SUMMARY

External Quality Assessment (EQA) or proficiency Testing (PT) is an essential part of providing quality laboratory diagnostic services, and participation in EQA is required for laboratory accreditation to ISO 15189 and ISO 17025. EQA is the inter laboratory comparison and performance evaluation that extends throughout all phases of the healthcare diagnostic testing cycle.

PRODUCT DESCRIPTION

We as pO_2 Accuracy EQA samples are 2.5 mL ampoules of tonometered bovine haemolysate that has identical oxygen saturation characteristics to fresh whole blood.

STORAGE AND STABILITY

The samples are dispatched frozen on ice packs and will thaw in transit.

Please analyse the samples as soon as possible (preferably the same day as receipt). If immediate analysis is not possible, please refrigerate the samples at 2-8°C on arrival (for no longer than 3 days), bringing the samples to ambient temperature (18-30°C) prior to analysis (for no longer than 8 hours). Do not freeze or return the sample to the refrigerator after this time.

PROCEDURE

- Samples should be left for at least 1 hour at ambient temperature (18-30°C) prior to analysis (<u>but not more</u> <u>than 8 hours</u>). <u>Do not</u> return to the refrigerator once exposed to room temperature.
- Immediately before use, shake the ampoule vigorously for at least 15 seconds to re-equilibrate the gases with the solution.
- 3. Swirl the ampoule gently to return liquid to the bottom. Allow bubbles to rise to the surface before opening the ampoule.

4. The vials are pre-scored; using gloves protect fingers with gauze or tissue, hold vial with the coloured dot facing towards you and securely snap off the neck of the ampoule in the opposite direction.

Analyse within 10 min after opening the ampoule.

Please refer to accompanying instruction letter, and figures 1 to 4 within this letter, for full details on sampling handling procedure.

Always wear gloves to avoid contamination.

LIMITATIONS OF PROCEDURE

The Weqas pO₂ Accuracy EQA samples require storage as described in STORAGE AND STABILITY and handling as described in PROCEDURE and accompanying instruction letter.

Accurate and reproducible results are dependent upon properly functioning instruments and reagents and the use of correct procedures.

ANALYTE RANGE COVERED

The haemolysate material should be assayed for **Blood Gas (pH,** H^+ , pCO_2 and pO_2), Standard Bicarbonate (SBCe) or Actual Bicarbonate, Base Excess or Base Deficit, sO_2 and Co-oximetry (tHb, COHb, MetHb and O_2 Hb).

! CAUTION!

- 1. For in vitro diagnostic use only.
- 2. This product is prepared from bovine material. Cattle used for bleeding are under veterinary control. Cattle have not been mixed with other cattle. No foot-and-mouth disease or rinderpest has been observed in these cattle. However, no test method can offer complete assurance that products derived from bovine source material are free from infectious agents.
- 3. This product should not be disposed of in general waste. Consult local environmental authorities for proper disposal.

Although every effort is made to ensure that the material is free from any known infectious agent, the samples should be handled as for clinical specimens.