



Co-oximetry EQA

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INTENDED USE

Weqas Co-oximetry EQA samples are for in-vitro diagnostic use as an external quality assessment material for testing of total haemoglobin (THb) and haemoglobin fractions for Co-oximeter analysers.

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

Weqas Co-oximetry EQA samples are sourced from a third party. The samples are prepared from a stromafree bovine haemoglobin solution. No dyes have been added to mimic haemoglobin fractions.

The samples are supplied in an ACU-Drop® container, which is a dual chambered device separating two solutions. To combine the fluids a button on the device is pressed. Once thoroughly mixed the sample is ready to use. Each vial contains 2 mL of solution after preparation. The samples have distinct levels that cover clinically relevant ranges for THb, oxyhaemoglobin (O₂Hb), carboxyhaemoglobin (COHb) and methaemoglobin (MetHb).

STORAGE AND STABILITY

Store samples at 2 - 8°C on receipt.

Wegas Co-oximetry EQA samples are stable at $2-8^{\circ}$ C for the two weeks of the distribution. Prior to analysis the samples must be brought to ambient temperature ($18-30^{\circ}$ C) for a minimum of 15 minutes, but for no longer than 60 minutes.

After sample preparation the solutions for measurement are stable for 15 minutes only at ambient temperature $(18-30^{\circ}\text{C})$.

STORAGE AND PROCEDURE FOR BATCHED SAMPLES

Store samples at 2 - 8°C on receipt. Samples are stable in storage at 2-8°C for 3 months.

At the start of the return window for each distribution remove samples from storage and bring relevant samples to ambient temperature (18-30°C) for a minimum of 15 minutes, but for no longer than 60 minutes. Assay as described in PROCEDURE.

PROCEDURE

Please refer to accompanying instruction sheet for full details on sampling procedure.

Always wear gloves to avoid contamination.

LIMITATIONS OF PROCEDURE

The Weqas Co-oximetry EQA samples require storage as described in STORAGE AND STABILITY and handling as described in PROCEDURE and accompanying instruction sheet.

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

APPROXIMATE RANGE COVERED

The Wegas Co-oximetry EQA samples cover a relevant pathological and analytical range.

| Analytes |
|---------------------------|
| Total Haemoglobin (THb) |
| Oxyhaemoglobin (O₂Hb) |
| Carboxyhaemoglobin (COHb) |
| Methaemoglobin (MetHb) |

! CAUTION!

- 1. For in vitro diagnostic use only.
- 2. Animal Blood Product. Bovine based materials do not carry biohazards to humans, such as HepB, HepC and HIV. This product is free from TSE.
- 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.

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