



POCT Cardiac EQA

INTENDED USE

Weqas *POCT Cardiac EQA* samples are for in vitro diagnostic use as an assayed quality control material; especially designed for application in External Quality Assurance Schemes to verify the precision and accuracy of POCT meters assaying Cardiac Markers.

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

The base material is human EDTA plasma, tested negative for HIV and Hepatitis B and C at donor level. Weqas *POCT Cardiac EQA* is a quality control material available in different levels, each with a known concentration of CK MB, a preparation of Troponin I/T/C complex and myoglobin from cardiac tissue. The pools are filtered aseptically, and an antibiotic added to maintain sterility. **Preservatives such as sodium azide are not added as these are known to inhibit certain immuno-enzymatic methods.** The plasma is dispensed aseptically into 0.5 mL aliquots and stored at -20°C until dispatched.

STORAGE AND STABILITY

The samples are dispatched frozen and will thaw in transit. Please ensure that the samples are well mixed before analysis. If the samples are not assayed on day of arrival, the samples should be stored immediately at 2-8°C and assayed within five days of receipt, ensure samples are brought to ambient temperature (18-30°C) before analysis. The samples are stable at -20°C for 12 months.

STORAGE AND PROCEDURE FOR BATCHED SAMPLES

The samples should be stored at -20°C on receipt. At the start of the return window for each distribution thaw the relevant samples at ambient temperature (18-30°C) for 24 hours and assay as described in PROCEDURE.

PROCEDURE

The EQA samples should be treated the same as patient specimens and run in accordance with the instructions accompanying the test system being used.

1. On day of assay remove the required samples from the freezer and leave to thaw at ambient temperature (18-30°C) for 15-30 minutes.
2. Gently mix the contents of each vial before sampling to ensure homogeneity.
3. Assay immediately.

Always wear gloves to avoid contamination.

Once EQA testing is complete, dispose of remaining sample according to local Health & Safety regulations. EQA materials should be used in accordance with local, National regulations or accreditation requirements.

ANALYTE LIST

The Weqas *POCT Cardiac EQA* samples cover a relevant pathological and analytical range.

Analyte
Troponin I
Troponin T
CKMB (mass)
Myoglobin

LIMITATIONS OF PROCEDURE

The *POCT Cardiac EQA* requires storage as described in STORAGE AND STABILITY and handling as described in PROCEDURE.

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

! CAUTION !

1. For in vitro diagnostic use only.
2. The base material has been tested in accordance with FDA regulations and found to be negative for HIV Ab, Hepatitis B and C.
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.