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Plasma Cardiac Markers EQA

INTENDED USE

Weqas *Plasma Cardiac Markers 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 Plasma Cardiac meters.

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 *Plasma Cardiac Markers EQA* is a quality control material available in different levels, each with a known concentrations 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 0.5ml aliquots and stored at -20°C until dispatched.

STORAGE AND STABILITY

Samples are dispatched on dry-ice and should be received frozen and on arrival immediately stored at -20° C.

Stored unopened at this temperature the product is stable for 12 months.

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 room temperature 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.

APPROXIMATE RANGE COVERED

The Weqas *Plasma Cardiac Markers EQA* samples cover a relevant pathological and analytical range as outlined below.

Analyte	Approx Range
Troponin I	0 – 3000 ng/L
CKMB (mass)	0 – 80 ug/L
Myoglobin	14 – 500 ug/L

LIMITATIONS OF PROCEDURE

The *Plasma Cardiac Markers 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.