



Serum Cardiac Markers EQA

INTENDED USE

Weqas Serum Cardiac Markers EQA samples are for in-vitro diagnostic use as an external quality assessment material for testing of Troponin T, Troponin I and CKMB.

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

1 ml volume supplied in sterile plastic tubes. The base material is human serum, tested negative for HIV and Hepatitis B and C at donor level. The pools are spiked with a source of recombinant CKMB and a preparation of Troponin I/T/C complex from cardiac tissue. The material is dispensed and stored at -20°C until dispatch.

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 4°C and assayed within five days of receipt, ensure samples are brought to room temperature 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 room temperature for 24 hours and assay as described in PROCEDURE.

PROCEDURE

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

1. Mix the sample well by gently inverting 5 to 6 times.
 2. Wear gloves and handle the sample as a normal patient sample.
 3. Carefully remove the lid from the sample.
- 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.

Always wear gloves to avoid contamination.

LIMITATIONS OF PROCEDURE

The Weqas Serum 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.

RANGE COVERED

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

Analyte	Approx Range
Troponin T	3-440 ng/L
Troponin I	2-600 ng/L
hsTroponin I	2-1250 ng/L
CKMB (mass)	0-120 µg/L
CKMB (activity)	0-180 IU/L

! 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.