



POCT HIV EQA

INTENDED USE

Weqas POCT HIV EQA samples are for in-vitro diagnostic use as an external quality assessment material for testing of HIV.

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

0.5mL volume supplied in sterile plastic tubes. The material has been prepared from human serum and do not include stabilisers or preservatives. The serum is dispensed and stored at -70°C until dispatch.

STORAGE AND STABILITY

The samples are stable for 6 days at room temperature and at 4°C.

The samples should be assayed on the day you receive them. If you are unable to assay the samples immediately upon receipt, please store at 4°C and assay within 4 days. Samples stored at 4°C prior to analysis must be brought to room temperature and assayed within 30 minutes.

PROCEDURE

1. Mix the sample well by gently inverting 5 to 6 times then gently swirling the vial for 5 to 10 seconds – ensure there are no air bubbles in the sample.
2. Wear gloves and handle the sample as a normal patient sample.
3. Assay the samples as if they were patient samples, but **DO NOT** use the chase buffer; this is for whole blood samples only. Follow the test procedure in the manufacturers' instructions provided with the kit.

4. Safely dispose of excess sample in accordance with local waste policy guidelines.

Always wear gloves to avoid contamination.

STORAGE AND PROCEDURE FOR BATCHED SAMPLES

The samples should be stored at -70°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.

LIMITATIONS OF PROCEDURE

The POCT HIV EQA samples should be analysed according to the instructions within this document. If there is evidence of microbial contamination or excessive turbidity in the product, discard the vial.

The POCT HIV 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.

APPROXIMATE RANGE COVERED

The Weqas POCT HIV EQA samples cover a relevant pathological and analytical range as outlined below.

Analyte	Approx Range
P24 Antigen	Positive/Negative
HIV-1 Antibody	Positive/Negative
HIV-2 Antibody	Positive/Negative

! CAUTION !

Human source material.

The base material is sterile human serum found negative at donor level for HIV Ab, Hep B surface Ag and Hep C.

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.