

POCT INR EQA

INTENDED USE

Weqas POCT INR EQA samples are for in-vitro diagnostic use as an external quality assessment material for testing of INR, suitable for use with the Abbott i-STAT, Roche CoaguChek XS, XS Plus & XS Pro and Siemens Xprexia Stride instruments.

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

0.3mL volume supplied in sterile plastic tubes. The material has been prepared from modified human plasma. The material is stored at -70°C until dispatch.

STORAGE AND STABILITY

Unopened thawed samples are stable for two (2) months in a refrigerator at 2-8°C. Once opened, the EQA samples are stable for 5 days at 2-8°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 2-8°C until analysis. Samples stored at 2-8°C prior to analysis must be brought to ambient temperature (18-30°C) and assayed within 30 minutes.

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 10 times – ensure there are no air bubbles in the sample.
2. Wear gloves and handle the sample as a normal patient sample.
3. **For Abbott & Roche instruments** - Test as a normal patient sample and continue at point 5.
4. **For Siemens Xprexia Stride instruments** – Select the IQC icon and scan the barcode below



Scan the barcode on the testing strip and insert into the instrument.

5. Carefully twist the cap to open the vial – see picture below. The cap may be inverted to reseal the sample after use.



6. Gently squeeze the vial to form a hanging drop and apply the sample to the test strip as per manufacturer instructions.
7. The result of the EQA 'INR' test is displayed.
8. Safely dispose of excess sample in accordance with local waste policy guidelines.

Always wear gloves to avoid contamination.

LIMITATIONS OF PROCEDURE

The Weqas POCT INR EQA samples should be analysed according to the instructions within this document.

The Weqas POCT INR 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.

ANALYTES COVERED

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

Analyte
INR

! CAUTION !

Human source material. Treat as potentially infectious.

Each unit of whole blood used in the manufacture of this product has been tested and found to be non-reactive for the presence of HBsAg, HCV, HIV and Syphilis.

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.