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# TDM EQA

**INTENDED USE**
Weqas Therapeutic Drug Monitoring (TDM) EQA samples are for in-vitro diagnostic use as an external quality assessment material for testing of Therapeutic drugs.

**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**
1ml 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 material is dispensed and stored at -20°C until dispatch.

**STORAGE AND STABILITY**
The samples should be assayed on the day you receive them.
**In case of delay in analysis samples should be stored at 4°C and assayed within 3 days.**
For samples stored at +4°C, ensure that the samples are brought to room temperature and mixed well before analysis.

**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. On day of assay remove the required samples from the fridge and leave to reach 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.**

**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.

**LIMITATIONS OF PROCEDURE**
The TDM EQA samples require storage as described in STORAGE AND STABILITY and handling as described in PROCEDURE.
TDM 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.
TDM 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 TDM EQA samples cover a relevant pathological and analytical range as outlined below.

| Analyte | Approx Range |
|---|---|
| Amikacin | 0-35 mg/L |
| Carbamazepine | 0-20 mg/L |
| Digoxin | 0-6 µg/L |
| Gentamicin | 0-5 mg/L |
| Lamotrigine | 0-30 mg/L |
| Lithium | 0-2.5 mmol/L |
| Methotrexate | 0-1.5 µmol/L |
| Phenobarbital | 0-65 mg/L |
| Phenytoin | 0-30 mg/L |
| Teicoplanin | 0-70 mg/L |
| Theophylline | 0-30 mg/L |
| Tobramycin | 0-15 mg/L |
| Valproic Acid | 0-175 mg/L |
| Vancomycin | 0-50 mg/L |

**! CAUTION !**
Human source material. Treat as potentially infectious. Each unit of base material used in the manufacture of this product has been tested by CE marked IVD methods and found to be non-reactive for the presence of HBsAg and antibody to HIV-1/2, HCV and HIV-1 Ag. While these methods are highly accurate, they do not guarantee that all infected units will be detected. Because no known test method can offer complete assurance that the hepatitis B virus, hepatitis C virus, human immunodeficiency virus (HIV) or other infectious agents are absent, all products containing human source material should be considered potentially infectious and handled with the same precautions used with patient specimens.