Serum Chemistry EQA

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INTENDED USE
Weqas *Serum Chemistry EQA* samples are for in-vitro diagnostic use as an external quality assessment material for testing of Serum Chemistry.

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
3.0 mL or 1.0 mL volumes supplied in sterile plastic tubes. The material has been prepared from sterile human serum, with an antibiotic added to maintain sterility. The serum is dispensed then stored at -20°C until dispatch.

STORAGE AND STABILITY
Unopened samples are stable for at least 2 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 samples stored at 2-8°C prior to analysis must be brought to ambient temperature (18-30°C) and assayed within 60 minutes.

Most of the analytes in the *Serum Chemistry EQA* samples are stable for at least one week at 2-8°C. The least stable analytes are CK, AST and ALT. To minimise analytical bias due to denaturation of these enzymes, please store at 2-8°C and assay within 2 days of receipt.

All analytes except ALP are stable for at least 12 months stored at -20°C.

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

Always wear gloves to avoid contamination.

STORAGE AND PROCEDURE FOR SAMPLES RECEIVED BY BULK DISPATCH
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 ambient temperature (18-30°C).

CK must be analysed 3-6 hours post defrost.
All other analytes must be analysed 24-48 hours post defrost.
Assay as described in PROCEDURE.

Please ensure that the samples are well mixed before analysis.

ANALYTES COVERED
The *Serum Chemistry EQA* samples cover a relevant pathological and analytical range as outlined on page 2.

LIMITATIONS OF PROCEDURE
The *Serum Chemistry EQA* samples should be analysed according to the instructions within this document. If there is evidence of microbial contamination in the product, discard the vial.

The *Serum Chemistry EQA* samples require 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 !
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 and antibody to HIV-1/2, HCV and HIV-1 Ag.

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.

ANALYTES COVERED

Analyte
Sodium
Potassium
Chloride
Bicarbonate
Urea
Creatinine
e-GFR
Glucose
Calcium
Adjusted Calcium
Phosphate
Total Protein
Albumin
Calculated Globulin
Magnesium
Urate
Lithium
Lipase
Osmolality
AST
ALT
ALP
CK
Gamma GT
Amylase
Pancreatic Amylase
LDH
Iron
TIBC
UIBC
Transferrin
Transferrin Saturation
Gentamicin
Serum Indices