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Serum Chemistry EQA

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
Samples are supplied as 3.5 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 4°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 room temperature and assayed within 1 hour.

Most of the analytes in the Serum Chemistry Scheme samples are stable for at least one week at 4°C. The least stable analytes are CK, AST and ALT. To minimise analytical bias due to denaturation of these enzymes, please store at 4°C and assay within 2 days of receipt.

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

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.

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.

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.

APPROXIMATE RANGE 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 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.

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.

APPROXIMATE ANALYTE RANGE COVERED

Analyte	Approx. Range Covered	Units
Sodium	101 - 165	mmol/L
Potassium	1.6 – 8.0	mmol/L
Chloride	73 - 123	mmol/L
Bicarbonate	7 - 28	mmol/L
Urea	1.5 - 25.0	mmol/L
Creatinine	25 - 600	µmol/L
e-GFR	<15 to 90	mls/min/1.73m^2
Glucose	1.4 - 25.0	mmol/L
Calcium	1.2 – 3.3	mmol/L
Adjusted Calcium	1.4 – 3.0	mmol/L
Phosphate	0.2 - 2.2	mmol/L
Total Protein	34 - 86	g/L
Albumin	20 - 53	g/L
Calculated Globulin	20 - 40	g/L
Magnesium	0.2 - 2.0	mmol/L
Urate	100 - 700	µmol/L
Lithium	0.05 - 2.0	mmol/L
Lipase	10 - 400	IU/L
Osmolality	190 - 390	mmol/kg
AST	5 - 300	IU/L IFCC
ALT	5 - 500	IU/L IFCC
ALP	25 - 400	IU/L SCE
CK	20 - 1200	IU/L SCE
Gamma GT	10 - 400	IU/L SCE
Amylase	15 - 800	IU/L
Pancreatic Amylase	20 - 160	IU/L
LDH	50 - 700	IU/L SCE
Iron	7 - 30	µmol/L
TIBC	28 - 82	µmol/L
UIBC	2 – 60	µmol/L
Transferrin	1.5 – 3.5	g/L
Transferrin Saturation	22 - 30	%
Gentamicin	1 - 8	µg/ml
Serum Indices	Icteric, Lipaemic, Haemolysed and 'negative' samples distributed.	