

INTENDED USE

Weqas General Urine Chemistry EQA samples are for in-vitro diagnostic use as an external quality assessment material for testing of Urine Chemistry analytes.

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

2.5mL volume for non-acidified samples & 0.5mL volume for pre-acidified samples are supplied in sterile plastic tubes. Separate pre-acidified samples are provided for the analysis of calcium, magnesium and phosphate. The material has been prepared from sterile urine from healthy donors, with an antibiotic added to maintain sterility. The urine is dispensed and stored at -20°C until dispatch.

STORAGE AND STABILITY

If you are unable to assay the samples immediately upon receipt, please store at 4°C until analysis. Samples stored at 4°C prior to analysis must be brought to room temperature prior to use.

Samples should be stored at -20°C for long term storage.

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.

LIMITATIONS OF PROCEDURE

The Urine Chemistry 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 Urine 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.

APPROXIMATE RANGE COVERED

The Weqas Urine Chemistry EQA samples cover a relevant pathological and analytical range as outlined below.

Analyte	Approx Range
Sodium	13 – 200 mmol/L
Potassium	9 – 137 mmol/L
Chloride	13 – 300 mmol/L
Urea	38 – 500 mmol/L
Creatinine	1 – 22 mmol/L
Glucose	0 – 40 mmol/L
Calcium	0.5 – 7 mmol/L
Phosphate	6 – 35 mmol/L
Protein	0 – 2 g/L
Protein /Creatinine Ratio	0 – 300 mg/mmol
Albumin	0 - 2000 mg/L
Albumin/Creatinine Ratio	0 – 200 mg/mmol
Magnesium	0.5 – 8.5 mmol/L
Urate	0.5 – 5.0 mmol/L
Osmolality	100 – 1000 mmol/Kg
Amylase	0 – 400 IU/L

! CAUTION !

Human source material.

The base material is sterile urine from 'normal' volunteers.

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.