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POCT Urinalysis EQA

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

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
5.0 mL volume supplied in sterile plastic tubes. The material has been prepared from human urine and an antibiotic added to maintain sterility. The urine is dispensed and stored at -70°C until dispatch.

STORAGE AND STABILITY
At 4°C glucose, protein, pH, SG, blood, nitrites and leukocytes are stable for 16 days. Ketone is stable for 1 month. Bilirubin is stable for 10 days. Creatinine is stable for 50 days and microalbumin is stable for 6 weeks.

The samples should be assayed on the day you receive them. If you are unable to assay the samples immediately, store at 4°C and analyse within 3 days. Samples stored at 4°C prior to analysis must be brought to room temperature and assayed within 30 minutes. Samples are light sensitive and such be protected from light until analysis.

PROCEDURE
Each POCT Co-ordinator will receive multiple samples for each POCT site / operator. 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 then gently swirling the vial for 5 to 10 seconds – ensure there are no air bubbles in the sample.
2. Wear gloves and handle the sample as a normal patient sample.
3. Carefully remove the lid from the sample.
4. Dip strip briefly into the sample and remove excess as would a patient sample.
5. Ensure the test area is completely covered.
6. Record the results according to your organisational policy.
7. Safely dispose of excess sample in accordance with local waste policy guidelines.
8. Results should be returned to the POCT Co-ordinator for your organisation.

The ward/operational site trainer should ensure that as many authorised users as possible participate in the scheme.

Always wear gloves to avoid contamination.

LIMITATIONS OF PROCEDURE
The POCT Urinalysis 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 POCT Urinalysis 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 WEQAS POCT Urinalysis EQA samples cover a relevant pathological and analytical range as outlined below.

Analyte	Approx Range
Glucose	0 - 60 mmol/L
Ketone	0 - 20 mmol/L
Protein	0 - 5 g/L
Haemoglobin	0 – 7500 µg/L
Specific Gravity	1.005 – 1.020
pH	6 - 8
Bilirubin	0 – 50 µmol/L
Urobilinogen	0 – 200 µmol/L
Leucocytes	0 – 500 µl esterase/L
Nitrites	0 – 40 µmol/L
Microalbumin	0 – 1000 mg/L
Albumin/creat	<3.4 - >34 mg/mmol

! 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.**