

### INTENDED USE

Weqas *POCT Creatinine EQA* samples are for in-vitro diagnostic use as an external quality assessment material for testing of Creatinine and eGFR.

### 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

0.5 mL volume supplied in sterile plastic tubes. The material is sterile lysed animal whole blood, with an antibiotic added to maintain sterility. The material is dispensed and stored at -20°C until dispatch.

### STORAGE AND STABILITY

The samples are stable for 72 hours at room temperature, for 14 days at 4°C and for 12 months at -20°C.

The samples should be assayed on the day you receive them. 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 and assayed within 30 minutes. For long term storage store samples 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 then gently swirling the vial for 5 – 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 white lid from the sample.
4. Gently squeeze the bottle to form a small hanging drop and apply the sample to the testing strip as per manufacturer instructions.
5. Safely dispose of excess sample in accordance with local waste policy guidelines.

**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

*POCT Creatinine 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 Creatinine 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 Creatinine EQA* samples cover a relevant pathological and analytical range as outlined below.

Analyte	Approx Range
Creatinine	50 - 700 µmol/l
eGFR	<15 – >90 mls/min/1.73m <sup>2</sup>

### ! CAUTION !

#### Animal source material.

The base material is lysed animal whole blood from certified healthy donor animals.

**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.**