Development of an External Quality Assessment Scheme for POCT Creatinine Whole Blood Meters

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Introduction
External Quality Assessment (EQA) is an essential part of assuring the quality of laboratory diagnostic services, and participation in EQA is a requirement for laboratory accreditation to ISO15189 and Point of Care (POC) accreditation to ISO22870. POCT whole blood Creatinine meters are increasingly used in settings such as Radiology, as a screen for possible kidney disease in the ‘normal’ population. This screen is used in the prevention of contrast-induced-nephropathy (CIN) where administration of (nephro-toxic) contrast media is required.

Aim
To develop and validate material for use in an EQA scheme for whole blood Creatinine and eGFR. To assess the material’s stability and commutability and to establish appropriate performance specifications for Creatinine and eGFR.

Method
Individual donor whole blood and lysed whole blood were assessed for stability at 20°C, 4°C and -20°C. The lysed blood was split into 3 pools with one pool left unadulterated, one pool spiked with 200 µmol/L Creatinine and one spiked with 500 µmol/L Creatinine. Long term stability at -20°C for 11 months was also assessed for the lysed blood.

Commutability of both blood products was assessed across a number of POCT whole blood Creatinine meters / devices and compared with an ID-GCMS method.

Thirty five sites in the UK were recruited to take part in the study. Each site was sent 3 samples at varying concentrations of Creatinine every 2 months. Human donor whole blood material was distributed for the first 6 distributions followed by lysed whole blood covering a Creatinine range of 80 – 700 µmol/L over an 18 month period.

Results & Discussion
CVs of between 16 and 6% were observed for the human donor material at Creatinine concentrations of 65 to 135 µmol/L respectively. Performance of lysed blood was similar to that of the human donor material with CVs of 6 to 16% at concentrations within the ‘normal’ Creatinine range and a CV of 10% at high concentrations. CVs of between 5 and 15% were observed for eGFR across a range of 10 to 90 mls/min/1.73m².

The lysed blood was found to be a more stable and suitable product with a stability of 21 days at 4°C and 11 months at -20°C.

An accuracy assessment of participants’ data on six pools compared with an ID-GCMS method showed a bias of +27% at a Creatinine concentration of 66.6 µmol/L with biases of between 3 and 6 % at concentrations above 200 µmol/L. The Weqas performance specification for POCT Creatinine in terms of total error (TE) was established as target value +/- 11%. This is wider than the TE used for Creatinine on Blood Gas analysers and Laboratory methods used for EQA programmes in the UK, however, this wider specification is a reflection of the clinical utility of the test.

The EQA scheme for Creatinine and eGFR is now well established with over 50 users and was recently accredited to ISO 17043.