Frimley Health NHS Foundation Trust

Berkshire and Surrey Pathology Services

The Need for Caution in Community iSTAT Chem8 Creatinine Assessment

B.Phillips , V.Genco , B.Buckman , M.Vasanthan , P.Nkuranga , FC.Riddoch , KJ.Heaney

Berkshire and Surrey Pathology Services, Frimley Health NHS Foundation Trust

AIMS

Investigate iSTAT Chem8 creatinine performance compared to local laboratory and POCT methods.

Evaluate the effectiveness of a software update in improving creatinine comparability at clinically elevated levels.

INTRODUCTION

Across the Berkshire and Surrey Pathology Services (BSPS) network, Abbott Alinity iSTAT handheld meters are routinely used by community teams (e.g. hospital-at-home, virtual wards) to enable Point of Care Testing (POCT) of electrolytes, metabolites and blood gases in patients' homes.

Complaints were received from multiple community services, reporting significant discrepancies in creatinine results between iSTAT Chem8 cartridges and the Abbott Alinity laboratory platform, despite both samples being drawn simultaneously and analysed on the same day. In all cases, the patient's laboratory creatinine was above the biological reference interval, and the iSTAT result reported a significant positive bias comparatively. No interfering substances (e.g. hydroxycarbamide) were identified as contributing factors.

Our clinically-led POCT service initiated a broader review of test performance in patient samples.

METHOD

Initial Clinical Review:

Patient selection and method: Patients with iSTAT Chem8 creatinine results >=200 umol/L from Jan 2024 to July 2024 were identified via the middleware (POCcelerator). Those with corresponding laboratory samples collected at the same time, were selected for analysis. (n=20).

iSTAT CLEW Version: Unknown, potentially multiple versions.

Comparison Method: Abbott Alinity c laboratory platform

Sample Type: Lithium Heparin (iSTAT), Serum (Lab)

Post-Software Upgrade Assessment:

Patient selection and method: Real-time review of patients undergoing routine blood gas sampling (including creatinine) in Frimley Park Emergency Department. 21 samples across a clinically-relevant range were selected and tested on two iSTAT devices (one with CLEW D49, one with CLEW D50) by POCT staff. This was in addition to the blood gas result as part of the routine standard of care, run by ED clinical staff.

iSTAT CLEW Version: D49 vs D50 assessed.

Comparison method: Radiometer ABL90 enzymatic creatinine.

Sample Type: Balanced Heparin (iSTAT and ABL90)

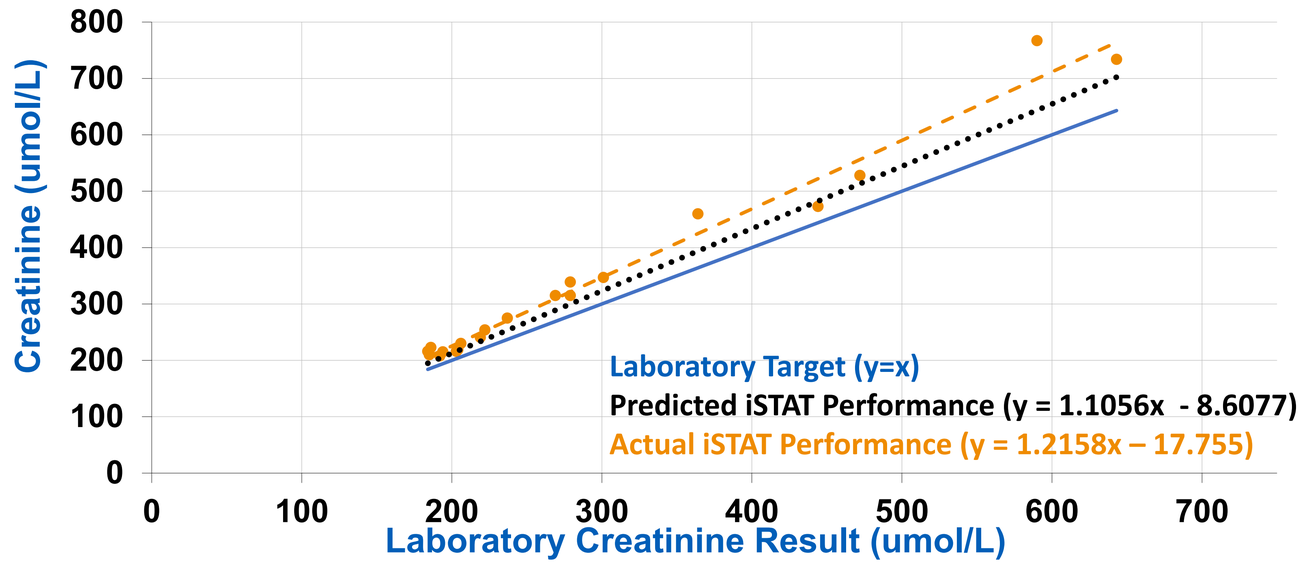
Statistical Analysis: Linear regression was used to compare methods

RESULTS – INITIAL REVIEW

The initial investigation revealed a positive proportional bias in iSTAT results. (Figure 1: Orange), compared to the laboratory. This exceeded the bias predicted from original implementation verification (Figure 2: Grey).

The manufacturer confirmed these findings and observed similar bias patterns across other comparator platforms.

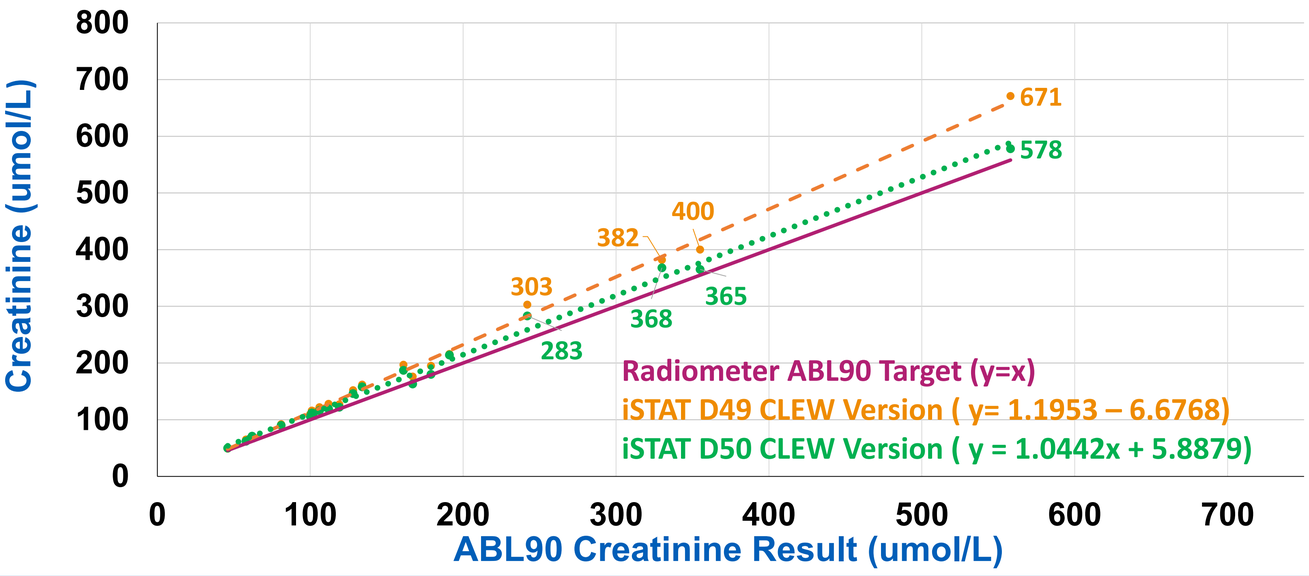
Figure 1: Real-world patient iSTAT results compared to paired laboratory samples (Pre-change)



RESULTS – POST CLEW VERIFICATION

The Radiometer ABL90 has previously shown to agree well to laboratory values (ABL90 = Lab Result*0.95 + 5.75 umol/L , n= 2255). The D50 CLEW software version Figure 2: Green), reduced iSTAT proportional bias by approximately 15%.

Figure 2: Patient iSTAT results compared to Radiometer ABL90 result from same sample. (Post-change)



DISCUSSION

This cases demonstrates the **value of a clinically-led and scientifically qualified POCT team in overseeing community diagnostic testing.** Without cross-service oversight, this trend may have gone unnoticed. The outcome has contributed to global improvements in test performance on the iSTAT via a CLEW update to recalibrate creatinine.

Our initial verification did not assess iSTAT performance above 200 µmol/L, and the significance of the existing bias was likely underestimated. This highlights the **importance of evaluating clinically relevant analytical ranges**—or at minimum, predicting performance and considering impact on the un-assessed range e.g. by extrapolating linear regression data.

The expected shift in creatinine performance was not documented in the CLEW update materials. CLEW software upgrades, released twice yearly, may adjust 'standardisation values'—effectively recalibrating the analyser.

Moving forward, **greater transparency from manufacturers on assay shifts is needed to support local assessments of significance and communication to users where appropriate**.

In this case, we informed users that patients monitored using iSTAT at the time of the CLEW update, or who return to iSTAT using services in the future, may appear to have lower creatinine and improved eGFR, despite no actual clinical change.

Pathology services should raise awareness of this potential clinical risk to all iSTAT users, particularly those not under their governance.

ACKNOWLEDGEMENTS

BSPS POCT Supported Community Services for their ongoing engagement. Frimley Park Emergency Department Staff for their support during practical work.

CONTACT

Bethan Phillips b.phillips5@nhs.net

I have no conflicts of interest to report

BSPS is a joint venture between: Ashford and St. Peter's Hospitals NHS Foundation Trust; Frimley Health NHS Foundation Trust; Royal Berkshire NHS Foundation Trust; Royal Surrey NHS Foundation Trust and Surrey and Sussex Healthcare NHS Trust

Legal entity host: Frimley Health NHS Foundation Trust