Frimley Health NHS Foundation Trust

Berkshire and Surrey Pathology Services

Collaborative Action to Restore Quality in POCT Lumira HbA1c

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INTRODUCTION

Our Point of Care Testing (POCT) team received a complaint from clinical users piloting POCT Lumira HbA1c in general practices (GPs). Users reported a clinically significant negative bias compared to results from samples collected at the same time and analysed by the local laboratory (Tosoh V11).

Aim: Perform a stepwise investigation to identify the root cause of Lumira HbA1c discrepancies.

METHOD OVERVIEW

Testing Method: **POCT Lumira Hba1c** (8 devices)

Comparison Method: **Laboratory Tosoh V11**

Patient Sample Selection: EDTA samples were retrieved from the laboratory (within 4 days of collection). Samples were excluded if chromatogram results indicated the presence of HbA1c variants.

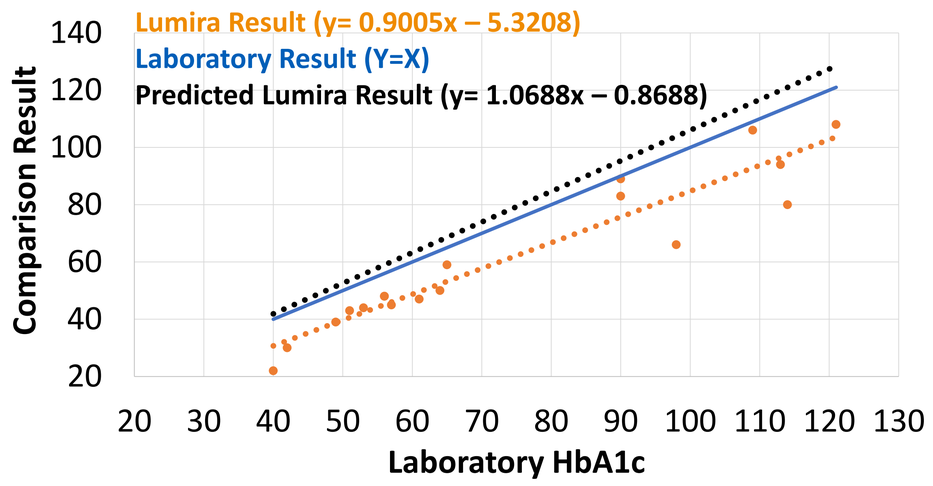
Statistical Analysis: Linear Regression, Shapiro Wilk

IN-SERVICE PATIENT RESULTS

Method: All patient results from the in-service devices were collated and compared to paired laboratory samples (Tosoh V11) where available (n=20).

Results: Paired results were reported from the devices: **1,2, and 4**. A clinically significant negative bias was evident (Figure 1). This differed significantly from expectations, as the implementation verification (performed on a single device) suggested a positive proportional bias versus the local laboratory method.

Figure 1: Comparison of Lumira HbA1c patient results to the local laboratory.



INTERNAL QUALITY CONTROL (IQC) REVIEW

Method: Routine weekly IQC results from all 8 devices since implementation were reviewed. All results passed within range.

All devices were retrieved for investigation. On this day, **device 2** failed to start and returned error readings.

IQC precision of the remaining 7 devices were assessed by X5 measurements on a single day. **The distribution CV% is shown in figure 2.**

Results: All IQC results were within manufacturer target range. Device 4 CV% was identified as a potential outlier.

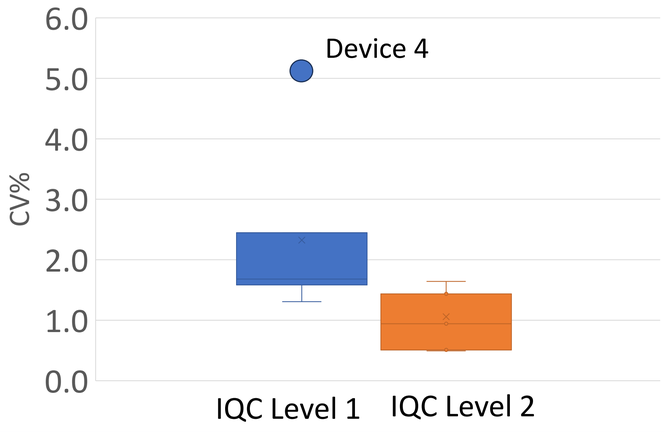


Figure 2 (Left): The distribution of CV% of IQC Level 1 (Target: 29 – 40 mmol/mol) and Level 2 (Target: 80 – 104 mmol/mol) run in replicate X5 on a single day.

REAGENT INVESTIGATION

Method: Two devices were selected. Four patient samples (Laboratory HbA1c results = 66 – 92 mmol/mol) were run on each device, using the current in-service reagent lot and a replacement reagent lot provided by the manufacturer.

Results: The in-service lot reported results on average 6.5% lower (95% CI [-9.44, -3.31]) lower than the replacement lot.

DEVICE INVESTIGATION

Method: Further testing was performed using the replacement reagent lot. Patient samples at 66 mmol/mol and 92 mmol/mol were run on each device.

Results: All IQC results passed within manufacturer target range.

66 mmol/mol target: 7/8 devices reported 62 – 65 mmol/mol and were considered clinically acceptable. **Device 2** reported 56 mmol/mol.

92 mmol/mol target: 6/8 devices reported 87 – 95 mmol/mol and were considered clinically acceptable. **Devices 2 and 4**, reported 80 mmol/mol.

CONCLUSION

Multifactorial cause of clinically significant negative bias:

1) Individual devices with poor performance (e.g. devices 2 and 4)
2) Reagent lot number exaggerating bias across all devices.

DISCUSSION

This case is as an example of a **step-wise, scientifically led investigation that prioritises patient safety**.

For teams conducting similar investigations, we'd recommend:

- **Collate evidence** to confirm complaints are accurate
- Assess for **known interferences or method limitations**
- Review historical and current **IQC performance**
- Evaluate the impact of specific **reagent** lots
- **Isolate individual devices** suspected to be affected**.**
- **Communicate** any required **service changes**
- **Risk assess the clinical impact –** of the incident and responses
- **Maintain clinical relationships** through regular updates.

In cases of unexpected findings, as seen here, **manufacturer engagement is essential to mitigate future risks**. The manufacturer responded by:

- Enhancing quality control checks in reagent production
- Identifying specific device faults and reviewing others from the same batch.

We **re-verified all Lumira HbA1c devices**, including replacements, using a minimum of five patient comparisons across the analytical range. **Service was reinstated with two patient samples compared to the laboratory weekly (in addition to manufacturer IQC)**, until clinical confidence was restored. We felt this necessary since devices with intermittent errors, or later found to be operating near performance limits, were still able to pass standard IQC procedures.

Moving forward, we will verify all new Lumira HbA1c devices in this fashion, and **review acceptance protocols** for other methods in our service – further considering **methodology complexity, the number of in-service devices, and the clinical significance of results.**

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I have no conflicts of interest to report

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