



Standard Operational Procedure (SOP) for Primary Care for managing patients affected by potentially unreliable HbA1c results from the Barking, Havering and Redbridge University Hospitals laboratory.

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Approved by: (name) Professor Andrew Deaner	Date: 01/08/2025
On behalf of: (Committee/Group): HbA1c Incident Stakeholder Group	
Job title of originator/author: Funmi Akinlade	
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Template V4 issued	

This document will be available (state where): BHRUT
Individual responsible for this document, including ensuring it is reviewed and updated by date given above, is: Funmi Akinlade
Previous version is archived (state where)

1. Introduction

The laboratories at Barking, Havering and Redbridge University Hospitals NHS Trust (BHRUT) identified a problem with the equipment used to test HbA1c. This issue may have resulted in HbA1c results being reported higher than they should have been in some patients.

The issue relates to HbA1c samples tested at the BHRUT laboratories during Jan - March 2024 and August 2024 – Jan 2025. Though it has been possible to ascertain the affected period, it is not possible at individual level to quantify the level of impact (i.e., it is not possible to state with confidence what the 'correct result' should have been). It is worth noting that the test result may not actually be wrong, this review is to ensure that any diagnostic decision based on results in the affected period is now correct.

This error may have resulted in some patients given a new diagnosis of non-diabetic hyperglycaemia, diabetes or treatment escalation for some patients

Consulted in the preparation of this document:

- HbA1c incident Stakeholder group
- London wide LMC
- Barking, Dagenham and Havering LMC
- Redbridge LMC
- NEL Clinical Leads

2. Definitions

BHRUT – Barking, Havering and Redbridge University Hospitals NHS Trust

3. Responsible personnel

Prof Andrew Deaner
Dr Godwin Simon
Dr Edel Casey
Sandra Moore
Funmi Akinlade
Dr Anju Gupta
Clare Bailey
Dr Ruth Crowley

4. Incident Information

BHRUT have published information on their website which provides access to consistent information:

Queries regarding this incident can be sent to bhrut.hba1c-gpqueries@nhs.net

BHRUT will contact the affected patients and invite them to book a blood test

BHRUT will review the patient lists to conclude where repeat blood testing has taken place. If a repeat blood test has not occurred after 2 contact attempts with the patient, BHRUT will notify the registered the practice.

Once results are available, please communicate the result to the patient.

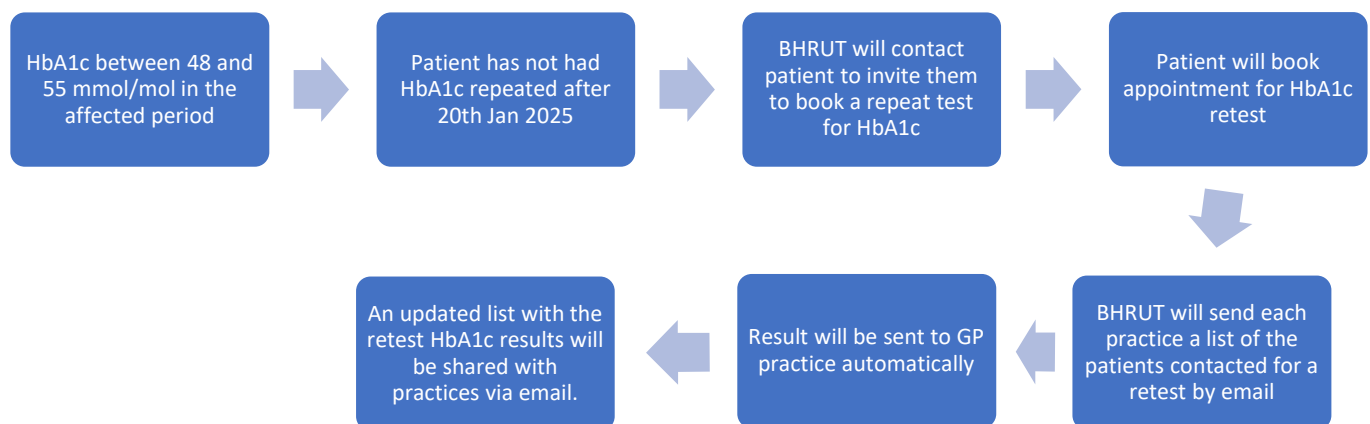
5. Prioritisation

The decision regarding which patients to prioritise for retesting was guided by a clinical reference group made up of senior clinical leaders from NEL ICB and BHRUT. Patients where there is the greatest likelihood that repeat testing may suggest a different categorisation will be prioritised.

Patients newly diagnosed with diabetes mellitus between 1st Jan 2024 and 13th March 2025 with HbA1c between 48 and 55 mmol/mol tested in the affected period will be contacted by BHRUT for retesting.

A. Newly diagnosed Diabetes

Patients with a new code of Diabetes between 1st Jan 2024 and 13th March 2025. Based on coding in GP data from NEL Intelligence and Insights search of NEL data.



B. Actions for GP practice

Please note:

[“Trinity Biotech Premier Hb9210™ HbA1c Analyser: Risk of Positive Bias and Updates to Instructions for Use \(IFU\), including use as a diagnostic aid in diabetes mellitus \(DSI/2025/003\) - GOV.UK](#)

The MHRA issued a Device Safety Information Report regarding the diagnostic reliability of the current HbA1c method used at BHRUT. BHRUT laboratories will be transitioning to a new testing platform by September/October 2025.

In the interim, please do not use the current HbA1c test alone to diagnose diabetes mellitus.

For recently diagnosed asymptomatic patients, further testing may be required. Please consider using fasting glucose or wait for further notification of implementation of the new method in Sept/Oct 2025 before repeating HbA1c.

We apologise for the inconvenience this may cause and appreciate your cooperation.

Reminder: *HbA1c should not be used to diagnose diabetes in individuals under 18 years of age.”*

Quote from MHRA document: “Trinity Biotech has committed to updating their Intended Use statement as follows, to include the use of the Trinity Biotech Premier Hb9210 HbA1c analyser as a diagnostic aide: The Premier Hb9210 System is intended for the quantitative measurement of haemoglobin A1c (HbA1c) in human capillary and venous whole blood. HbA1c is used for the monitoring of long-term glycaemic control in individuals with diabetes mellitus, and as an aid to diagnosis of diabetes mellitus, in accordance with applicable clinical guidelines. For in vitro diagnostic use only.”

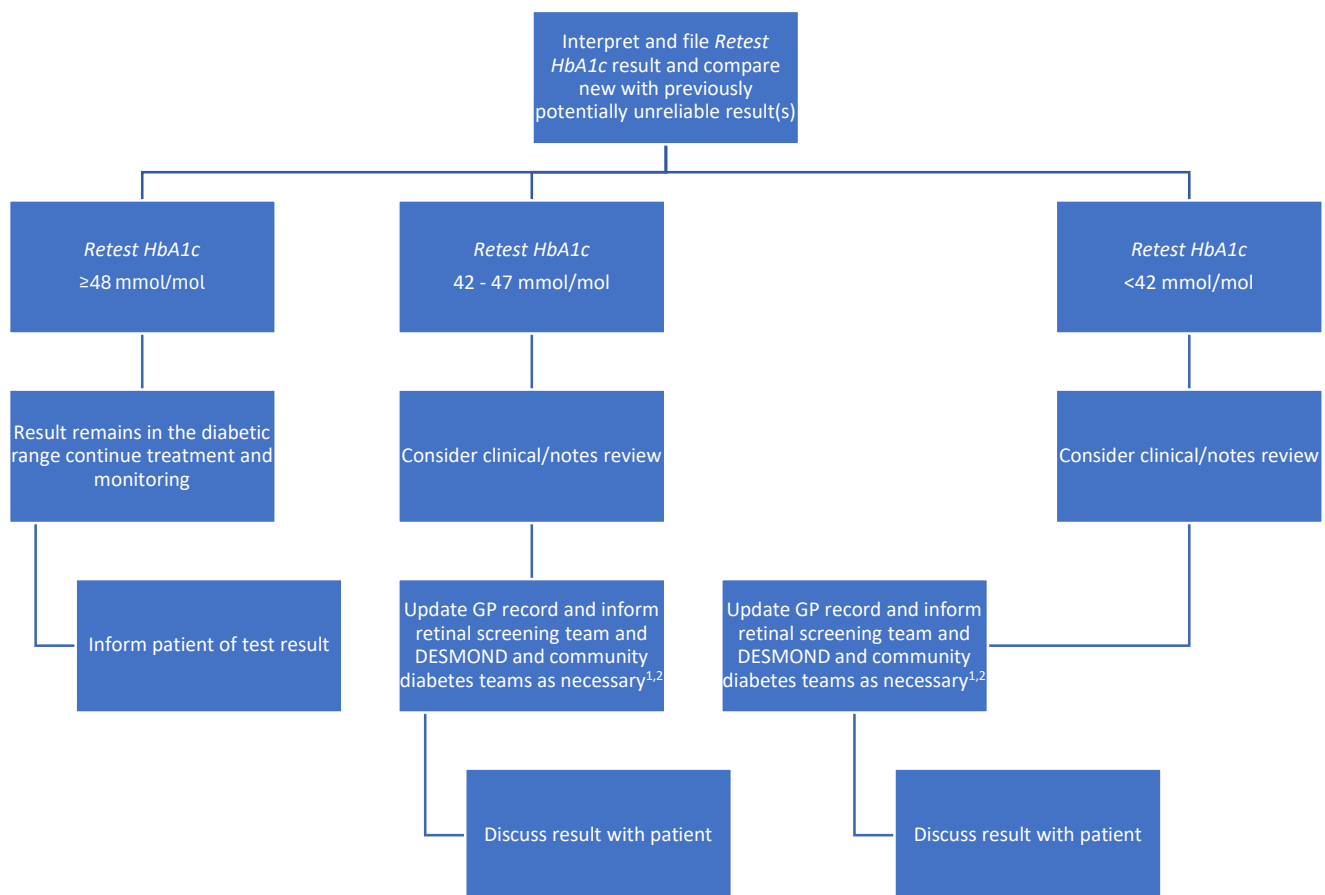
Hence Hba1c can continue to be used at this time for monitoring of long-term glycaemic control in patients with a known/established diagnosis of diabetes.

Reference

MHRA Device Safety Information – DSI/2025/003

Trinity Biotech Premier Hb9210 HbA1c Analyser: Risk of Positive Bias and Updates to Instructions for Use

Available at: <https://www.gov.uk/drug-device-alerts/trinity-biotech-premier-hb9210-hba1c-analyser-risk-of-positive-bias-and-updates-to-instructions-for-use-ifu-including-use-as-a-diagnostic-aid-in-diabetes-mellitus-dsi-slash-2025-slash-003>



Notes:

¹SNOMED codes

The SNOMED code on the patient record if inaccurate will need to be removed from the record. Please use caution when considering any changes in the SNOMED coding of a patient. There is a high risk of harm if DM coding is inappropriately removed from a patient's record. **Practices should remove all inaccurate diabetes codes from the records and add the code 185981001 [Error entry deleted (finding)] with a freetext comment to explain that the code of diabetes was removed due to laboratory recording a falsely high HbA1c in error and subsequently found not to have had diabetes into each entry.**

“Diagnosis of “X” made on this date based on laboratory recording a falsely high HbA1c in error. Patient subsequently found not to have had diabetes. SNOMED code removed from record for the purposes of accuracy. Patient informed and part of the process of correction.”

Where a patient is deemed not diabetic, please ensure that they are removed from the DM register. If after removing the SNOMED code, the patient is still on the register, please check what code is triggering this.

²Clinical Review

When reviewing these patients please consider, past HbA1c trend, lifestyle changes, interventions, medications (esp. not prescribed) and consider the time interval between results.

Please ensure you follow your clinical rationale. Some patients may require further testing after a time interval. If there are any concerns regarding the diagnosis please consider contacting bhrut.hba1c-gpqueries@nhs.net

Where a patient is taken off the diabetes register please inform any other services, including North East London Diabetes Eye Screening Programme.
Phone: 0208 510 5911 / Email: eyescreening@nhs.net).

It is important that you include the patient's demographic information and clearly state that the request is secondary to the laboratory HbA1c incident (See appendix B for a template email).

6. Special Considerations for Non-Priority Patients

- A. Newly diagnosed patients with diabetes who have already had a repeat test since 20th Jan 2025
→ Please review in the light of flowchart B.
- B. Patients with HbA1c ≥ 48 mmol/mol but not coded as diabetes:
→ May need **two further HbA1c tests** to confirm diagnosis.
- C. Medication Changes based on Unreliable Result:
→ Clinical review needed to check for harm (e.g., medication adjustment).

7. Communication to patient

Regardless of whether a clinical review is considered indicated, steps should be taken to inform the patient of their new result, and a review should be booked if the patient wishes to discuss this with a clinician. Please see Appendix B for patient facing letter that can be given to patients to support those incorrectly diagnosed with diabetes after review of symptoms and medical notes.

Please see link to patient information regarding this incident:

[Retesting of some patients newly diagnosed with diabetes | Latest news | BHR Hospitals](#)

Patient-related complaints can be directed to our Patient Advice and Liaison Service (PALS) as per normal process.

<https://www.bhrhospitals.nhs.uk/askpals>

Access to psychological support:

Talking Therapies is a free and confidential NHS service for adults registered with a GP in Barking and Dagenham, Havering, Redbridge and Waltham Forest. Talking Therapies are free, confidential NHS services for adults that can help with a range of problems such as depression, anxiety, stress, bereavement and relationship problems. Patients can self-refer to the local talking therapies service by calling the telephone number listed below.

<https://www.talkingtherapies.nelft.nhs.uk/how-to-refer-to-our-service>

For more information, please go to b.link/bdcovidchat (Monday-Friday, 8am-8pm) or call 0300 300 1554 option (Monday-Friday, 9am-5pm).

For urgent mental health problems call 0800 995 1000 (24 hours a day /7 days a week)

8. Reporting patient harm

After each clinical review, or at an earlier point if appropriate, a note should be made of any consequences encountered by a patient because of this clinical incident.

Consideration should also be given to whether any interventions/actions were made based on the potentially unreliable result which would not have otherwise been clinically indicated.

GP practices are requested to keep a list of the NHS numbers of patients where there has been potential harm. These patient cases will be analysed as part of the harm review process. The details of the harm review process are still to be determined.

9. Advice and Guidance

Any concerns about diagnostic and/or therapeutic changes can be sent to the GP queries email: bhrut.hba1c-gpqueries@nhs.net

Questions about diabetes management outside of this HbA1c incident should be referred to endocrinology via advice and guidance.

10. Provision of information to practices

BHRUT will provide to practice teams a list of their registered patients who had results in the affected time and:

1. Have a new diagnosis diabetes between Jan 2025 and 13th March 2025
 - a. At the start of the retest process
 - b. Once retest HbA1c results are available
2. Patients with HbA1c ≥ 48 mmol/mol not coded with diabetes.
3. Patients who did not respond to BHRUT's proactive recall programme for blood retesting.

11. Changes from previous version

Detail of revision	Reason for change
Removed harm review template	Harm review will take place following a different format
Included patient facing letter for those misdiagnosed with diabetes.	Advice from local LMC
Updated flowchart to include communication with DESMOND and/or other community teams	Discussion within working group
Updated advice for practices when amending SNOMED codes where the patient is found to not have diabetes	Advice form CEG
Included update from MHRA about risk of positive bias with Hb9210 HbA1c analyser.	MHRA alert DSI/2025/003

APPENDIX A

Email to be sent to Diabetes Eye Screening Programme

North East London Diabetes Eye Screening Programme.

Email: eyescreening@nhs.net).

RE: BHRUT HbA1c incident

Dear colleague,

Following the review of HbA1c results, we have amended this patient's record. This patient is no longer on the Diabetes register and should be removed from automatic recall for the Diabetes Eye Screening Programme. This is as a consequence of the BHRUT HbA1c incident.

First Name:

Surname:

NHS number:

DOB:

Sex: Male ☐ Female ☐

Your sincerely,

xxxxxx

APPENDIX B: This letter may be provided to the patient in the event of a diabetes misdiagnosis, following retesting and a review of clinical symptoms and medical notes

Chief Medical Officer
Trust Headquarters
Queen's Hospital, Rom Valley Way
Romford
Essex RM7 0AG
July 2025

Your diabetes diagnosis

Dear patient,

After we identified an issue with equipment used in our laboratories to analyse blood tests used to diagnose and monitor diabetes, we asked you to have a repeat blood test.

Following a careful review of this test, and of your symptoms and medical notes, we can confirm that you do not have type 2 diabetes.

Please be reassured we have introduced safeguards to prevent this from happening again.

I understand this will have been a worrying time for you, and I'm sorry for any distress this has caused. Below are the contact details for services that can provide support or if you'd like to raise any concerns.

Feedback or concerns

To make a comment or raise a concern, please contact our Patient Advice and Liaison Service (PALS).

www.bhrhospitals.nhs.uk/askpals

Psychological support

Talking Therapies is a free, confidential NHS service for adults registered with a GP in Barking and Dagenham, Havering, Redbridge, and Waltham Forest. They can help with issues such as stress, anxiety, depression, bereavement, and relationship difficulties.

www.talkingtherapies.nelft.nhs.uk/how-to-refer-to-our-service

For more information or general advice, visit <https://www.talkingtherapies.nelft.nhs.uk/covid-19-talking-therapies-emotional-wellbeing-live-chat-support> (Monday–Friday, 8am–8pm) or call **0300 300 1554 (option 1)** (Monday–Friday, 9am–5pm).

If you are experiencing an urgent mental health crisis, please call **0800 995 1000** (24 hours a day, 7 days a week).

Kind regards,
Andrew Deaner

**Chief Medical Officer
Barking, Havering and Redbridge University Hospitals NHS Trust**