NHS
Barking, Havering and Redbridge
University Hospitals
NHS Trust

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

Dear all,

We would like to provide an update regarding the recent HbA1c incident.
In **May 2025**, patients with a new diagnosis of diabetes and an HbA1c result between **48–55 mmol/mol** were contacted and invited for a repeat HbA1c test. Each GP practice has received a full list of affected patients, including:

- Patients with HbA1c results between 48–55 mmol/mol who were invited by **BHRUT** to book a retest.
- Patients with HbA1c results in the same range who have had **more recent HbA1c tests** (post-incident period) using assays with acceptable performance. These patients were **not recalled**.

An **updated SOP** is attached to support the review of each patient's diabetes status. It is expected that these reviews will be incorporated into **routine annual diabetes reviews**, or conducted sooner if clinically indicated. For further clinical input, specialist diabetologist advice is available via:
bhrut.hba1c-gpqueries@nhs.net

MHRA Device Safety Information
The **MHRA** has issued a Device Safety Information Report regarding the diagnostic reliability of the **Trinity Biotech Premier Hb9210 HbA1c analyser** currently used at BHRUT.
MHRA Alert: Trinity Biotech Premier Hb9210 HbA1c Analyser
BHRUT laboratories will transition to a **new testing platform** by **September/October 2025**.

Clinical Guidance (Interim)
Until the new platform is implemented:

- **Do not use the current HbA1c test alone** to diagnose diabetes mellitus.
- For **recently diagnosed asymptomatic patients**, consider:
  - Using **fasting glucose** testing, or
  - Waiting for the new method before repeating HbA1c.

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

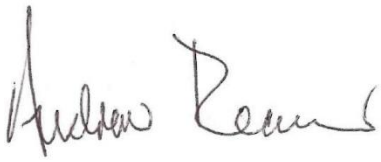
Equipment Update
Trinity Biotech has committed to updating the Intended Use statement for the Premier Hb9210 system to clarify its role as a **diagnostic aid**:
"The Premier Hb9210 System is intended for the quantitative measurement of haemoglobin A1c (HbA1c) in human capillary and venous whole blood. 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."

HbA1c testing **remains appropriate** for **monitoring** long-term glycaemic control in patients with an **established diagnosis** of diabetes.

We sincerely thank all GP practices for their collaboration and support in this system-wide response. Your engagement has been vital in ensuring timely identification and follow-up of affected patients. BHRUT continues to work closely with **NHS England**, the **MHRA**, and other affected trusts to maintain full oversight and transparency. To date, we have received only a small number of queries from GP practices and **no patient complaints**. If patients raise concerns, please be assured that **PALS** has been fully briefed and will manage queries appropriately.

For any further questions, please contact: **GP Liaison Manager**: janet.bartlett@nhs.net.

Yours faithfully



Professor Andrew Deaner, Chief Medical Officer
On behalf of HbA1c Incident Recovery Working Group