



# DEVICE SAFETY INFORMATION (DSI)

## 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)

**Specialities:** Endocrinology, Diabetology and metabolism, General Practice and Pathology

### DEVICE DETAILS

The Trinity Biotech Premier Hb9210 HbA1c analyser is a High Pressure Liquid Chromatography based laboratory system intended for the quantitative measurement of haemoglobin A1c (HbA1c) in human capillary and venous whole blood, used for the monitoring of long-term glycaemic control in individuals with diabetes mellitus.

### AFFECTED LOT SERIAL NUMBERS

All Trinity Biotech Premier Hb9210 HbA1c Analyser (Product Code: 42790, branded Menarini).

### MANUFACTURED BY

Trinity Biotech and distributed in the UK by A. Menarini Diagnostics.

## Summary

The MHRA has received reports describing a positive bias in HbA1c results delivered by the Trinity Biotech Premier Hb9210 HbA1c analyser, which has resulted in patients being incorrectly diagnosed as pre-diabetic or diabetic. The MHRA is working closely with the manufacturer, Trinity Biotech, to resolve this. In addition, Trinity Biotech, has committed to updating the Intended Use statement in the Instructions for Use (IFU), to include the use of the analyser as a diagnostic aide, and to provide further clarity regarding the frequency of preventative maintenance required to ensure the consistent performance of the analyser.

### Advice for Healthcare Professionals:

- the Trinity Biotech Premier Hb9210 HbA1c analyser IFU Intended use statement will be updated to state that results from the analyser can be used as an aid to the diagnosis for diabetes mellitus
- where HbA1c measurements are taken, ensure that you are familiar with the information presented in the recent Field Safety Notices (FSNs) (see below), issued by the manufacturer, and the Operator's Manual, to use the analyser accurately (refer to 'Explanation of identified safety issue' section below)
- if you are using the Trinity Biotech Premier Hb9210 HbA1c Analyser and notice a change in the performance of the analyser that falls outside the manufacturer's expected tolerance, please report the details to Trinity Biotech and the MHRA. Please see our reporting section below for details of how to report to the MHRA
- it is advised to closely monitor performance with independent Quality Control material, and to consider appropriate corrective action if significant changes in performance are detected
- consider whether recalling and retesting is required for any patients newly diagnosed as diabetic between April 2024 to the present

### Advice for Healthcare Professionals to Provide to Patients:

- to seek medical attention immediately if adversely affected following any changes to medication, such as hypoglycaemia (shaking/trembling, sweating, confusion, loss of consciousness) or hyperglycaemia (excessive thirst, blurred vision recurrent infections)

### Advice for Distributors:

- please ensure that end users are familiar with this DSI, the FSNs and the relevant manufacturer's IFU

## Explanation of identified safety issue

The MHRA has received reports from some NHS Hospital Trusts and EQA (External Quality Assurance) providers describing a positive bias in HbA1c results delivered by the Trinity Biotech Premier Hb9210 HbA1c analyser. These reports have ranged from discrepant HbA1c results between analysers, calibration issues, positive EQA, and longitudinal patient results, and in some cases has resulted in patients being incorrectly diagnosed as pre-diabetic or diabetic.

The MHRA has worked closely with the manufacturer to resolve these issues and [three FSNs](#) have been issued to affected customers informing them of the positive bias issue, including details of the manufacturer's investigation and actions to be taken. In addition,

the manufacturer has made efforts to further reduce the risk of positive bias and is continuing to work with labs in the field to verify correct operation and instrument performance.

The positive bias was first reported in April 2024, and while improvements have been made, there is evidence that the positive bias may still be occurring in some laboratories. MHRA note that some NHS trusts have already undertaken patient recall action and retesting. We therefore advise healthcare professionals to consider if a patient recall might be required for individuals newly diagnosed as diabetic or pre-diabetic since April 2024.

The manufacturer will also be updating their IFU to provide further clarity regarding the frequency of preventative maintenance required to ensure the consistent performance of the analyser. This will include the following:

- semi-Annual preventative maintenance must take place every 6 months or 15,000 injections
- annual preventative maintenance must take place every 12 months or 30,000 injections

In addition, 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 hemoglobin A1c (HbA1c) in human capillary and venous whole blood. HbA1c is used for the monitoring of long-term glycemic 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'.*

If you notice any carryover issues, or further positive bias, please notify the manufacturer immediately, and also submit a Yellow Card report to the MHRA.

### Reporting advice

Healthcare professionals should report incidents:

- in England and Wales to the [Yellow Card website](#) or via the Yellow Card app
- in Scotland to [Incident Reporting & Investigation Centre \(IRIC\)](#) and their local incident recording system

- in Northern Ireland to the Yellow Card website in accordance with your organisations medical device policies and procedures

### **Additional information:**

You can [sign up](#) to receive email updates on alerts and device safety information from the MHRA.

You can [sign up](#) to receive our monthly roundup of safety communications.

For any enquiries, please contact [info@mhra.gov.uk](mailto:info@mhra.gov.uk)

### **Stakeholder engagement:**

- Trinity Biotech
- Menarini
- NHS Trusts
- NHS England