

# Does your HbA1c immunoassay package insert contain a boxed warning for HbF interference?

## **IMMUNOASSAY BOXED WARNING**

This device has significant negative interference with fetal hemoglobin (HbF). HbA1c results are invalid for patients with abnormal amounts of HbF including those with known Hereditary Persistence of Fetal Hemoglobin.

## If so, how do you know your HbA1c results are accurate?

**BIO-RAD**

# The Impact of Fetal Hemoglobin on HbA1c Results – A Patient Case Study\*

## Introduction

A patient sample is run on two HbA1c methods: HPLC (Bio-Rad VARIANT II TURBO System) and immunoassay.

## Results

- The Bio-Rad HPLC method detects the presence of HbF (22.4%) and reports an HbA1c result of 6.9% which leads to a diabetes diagnosis and patient treatment per ADA guidelines.\*\*
- The immunoassay method cannot detect the presence of HbF and reports an HbA1c result of 4.7% which leads to no diabetes diagnosis and no treatment per ADA guidelines.\*\*

## Discussion

The same patient sample run on two different HbA1c methods produces different patient outcomes. How is this possible?

### Different technologies lead to the observed difference between the two methods.

#### Bio-Rad HPLC

- HbA1c results are valid and reportable on the VARIANT II TURBO System in the presence of HbF up to 25%.
- The VARIANT II TURBO detects the presence of HbF (22.4%) and its chromatogram provides a complete patient profile to clinicians.

**HbA1c testing methods that don't detect elevated levels of HbF might lead to misdiagnosis and unnecessary or delayed patient treatment.**

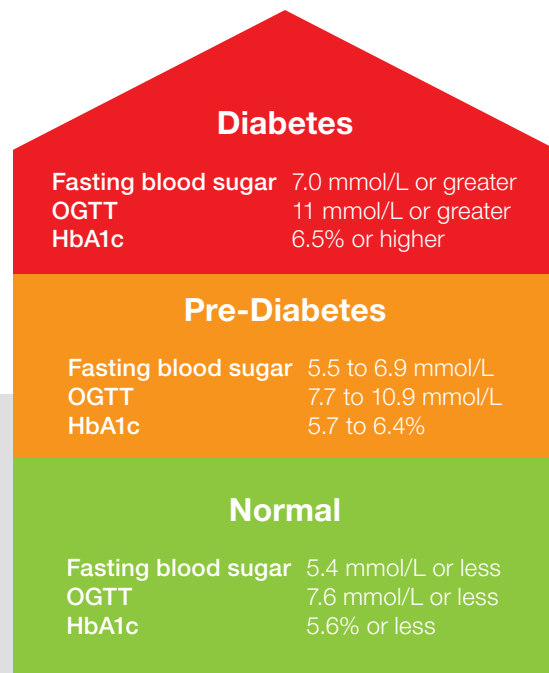
#### Immunoassay

- HbA1c results are invalid on immunoassay methods in the presence of HbF >7% due to interference. Specimens containing high amounts of HbF (>7%) may result in lower than expected mmol/mol HbA1c values (IFCC) and % HbA1c values (NGSP).
- Glycated HbF is not detected by the assay because the immunoassay antibodies only recognize HbA1c and not glycated HbF as it does not contain the  $\beta$ -chain that characterizes HbA1c.

Per the immunoassay boxed warning, the 4.7% HbA1c immunoassay result is invalid and should not be reported due to significant negative interference from HbF. In this scenario the critical question is: **how would you know that the HbA1c immunoassay result is invalid if immunoassay methods do not detect HbF?**

#### Conclusion

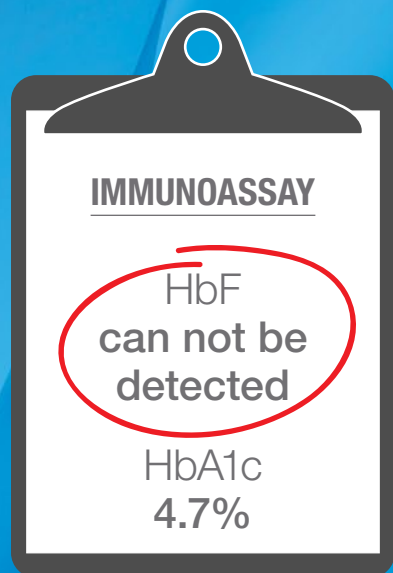
In this patient case study, only one HbA1c result is valid and reportable – the 6.9% Bio-Rad HPLC result produced by the VARIANT II TURBO System.



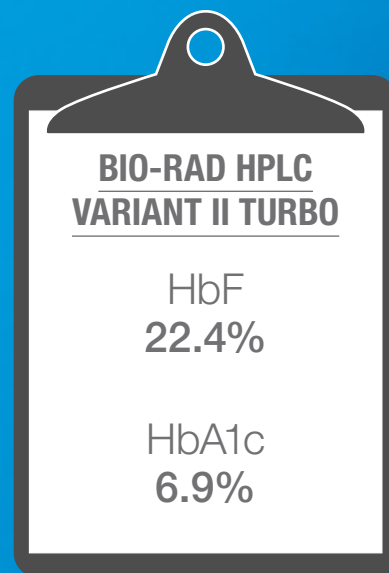
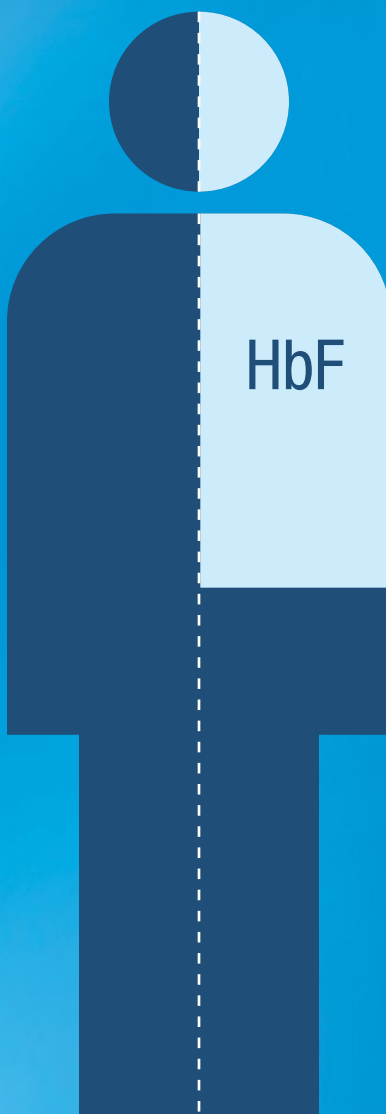
\* Data on file at investigating laboratory.

\*\* Source: American Diabetes Association Guidelines.

Same patient sample, different outcomes.  
How is this possible?



**✗ No Treatment**



**✓ Treatment**

**Bio-Rad HPLC detects HbF  
for a diagnosis you can trust**

# Bio-Rad HbA1c for the Complete Patient Picture

Because Missing One Diagnosis Is One Too Many



**Proven Power**  
D-10 Hemoglobin Testing System

No HbF interference up to 10%



**For a Demanding HbA1c Workload**  
VARIANT II TURBO Hemoglobin Testing System

No HbF interference up to 25%



**Smart HPLC**  
D-100 Hemoglobin Testing System

No HbF interference up to 30%



**Bio-Rad Laboratories, Inc.**

For further information, please contact the Bio-Rad office nearest you or visit our website at [www.bio-rad.com/diagnostics](http://www.bio-rad.com/diagnostics)

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