

<b>DATE:</b>	14 October 2025
<b>TO:</b>	All Zones
<b>FROM:</b>	Clinical Biochemistry, Alberta Precision Labs (APL)
<b>RE:</b>	<b>Hemoglobin A1c (HbA1c) Assay Update</b>

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### Key Message

- **Effective October 21<sup>st</sup> 2025**, all sites reporting Hemoglobin A1c (HbA1c) in Alberta will transition from the 3<sup>rd</sup> generation Roche Diagnostics HbA1c assay to the 4<sup>th</sup> generation Roche HbA1c assay.
  - Testing sites: Chinook Regional Hospital Laboratory, Medicine Hat Regional Hospital Laboratory, Grande Prairie Regional Hospital Laboratory, Calgary Diagnostic and Scientific Centre, and Edmonton Base Laboratory
- The upper limit of reporting will change from 20.1% to 18.3%. There will be no change to the lower reportable limit of 4.2%.
- There is no change to ordering, sample collection or routing processes for HbA1c.
- There is no impact to the APL Point of Care Testing (POCT) Siemens DCA Vantage HbA1c Program or result interpretation.

### Background

- The Roche 4<sup>th</sup> generation reagent is analytically and clinically equivalent to the 3<sup>rd</sup> generation reagent.
- As a reminder:
  - HbA1c is a measure of glycated HbA and reflects glucose control. Altered hemoglobin (e.g. hemoglobinopathies, methemoglobin) and conditions that influence red blood cell (RBC) longevity (e.g., thalassemia, iron deficiency anemia) or rates of glycation may impact the interpretation of HbA1c.
  - Patients with elevated levels of HbF (>7%) will have falsely low HbA1c levels when measured by this immunoassay.
  - In patients with altered hemoglobin and conditions influencing RBC longevity, consider alternative tests to evaluate glycemic control (e.g. fasting glucose, fructosamine or a 2-hour glucose tolerance test).

### How this will impact you

- Results exceeding 18.3% will be reported as >18.3%.

### Action Required

- No actions required.



**Questions/Concerns**

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**Approved by**

- Dr. Kate O'Connor, Medical Director, South Sector, APL, on behalf of Dr. Carolyn O'Hara, Interim Chief Medical Laboratory Officer, APL