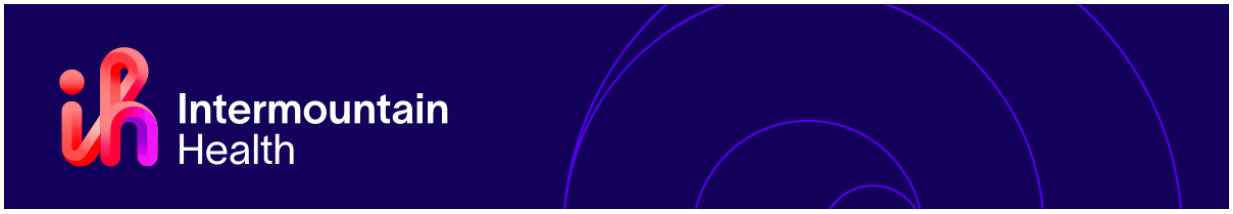
Item	Description
Author/Owner	Antonio Gonzalez
Audience	Employed physicians/APPs in Canyons and Desert
Channel	Outlook email via Professional Staff Services
Email Date	4/4/24
Approvers	Cara Camiolo
Pre-read Sent To	Leslie Reed, Mandy Anderson, Sterling Bennett, Sarah Ilstrup, Emily Shake

Subject line: Changes in HbA1C Methodology



This message is being sent to all physicians and APPs in the Desert and Canyons regions on behalf of Cara Camiolo, MD, Chief Medical Officer for the Desert Region, and Robert Hoesch, MD, Chief Medical Officer for the Canyons Region.

Dear Physicians and APPs,

Intermountain Health is in the process of transitioning the laboratory clinical chemistry instruments from the legacy Abbott Architect instruments to the new Roche instruments. Changes to the cardiac marker tests were well understood. As we have gathered more patient data, we have observed that hemoglobin A1C testing is impacted and we would like to share those details with you. We are changing from an enzymatic to immunoassay method. Both methods are National Glycohemoglobin Standardization Program-certified methods.

The switch is happening in phases. As of March 27, 2024, the following sites have switched A1C methodology to immunoassay:

- Central Laboratory
- McKay Dee

- Utah Valley
- Primary Children's
- Primary Children's Lehi (new lab)

LDS, Alta View, and Riverton Hospitals will be transitioning in early May. By late 2024/early 2025, the rest of the labs in legacy Intermountain will transition to the new instrumentation and new method. There are no changes in the collection requirements or the ordering pathway.

There is a recognized difference in the results when the enzymatic assay is compared to the immunoassay. Compared to a gold standard, the current enzymatic method of testing reads 0.1 or 0.2 lower. That means the test misses a few prediabetes or diabetes patients. The new immunoassay reads 0.2 or 0.3 higher, which means the test will capture more patients. This change is a move toward higher sensitivity and lesser specificity. We recognize that this will affect individual patients and their diagnosis and treatment regimens. We wanted you to be aware so that you can counsel your patients when needed. **In summary, the change from one assay to another will not affect all patients but may measure hemoglobin %A1C higher by up to 0.2 or even 0.5 for some patients.**

We will continue to use the reference range based on the ADA guidelines for interpretation of results.
Comments below are attached to each A1C results.

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The American Diabetes Association considers an A1c of 6.5% or
greater to be diagnostic of diabetes when confirmed by repeat
testing on a different day.

An A1c of 5.7 to 6.4% indicates an increased risk of developing
diabetes. These guidelines do not apply to pregnant women or
children. Ref: Diabetes Care 2010;33:S62-9.

If A1c and estimated average glucose do not match clinical
picture, consider altered RBC turnover and/or variant hemoglobin.
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If you have any questions, please contact Dr. Sterling Bennett, Senior Medical Director, Pathology and Laboratory Medicine and Medical Director, Central Laboratory.

Sincerely,
Cara Camiolo, MD
Chief Medical Officer - Desert Region

Robert Hoesch, MD
Chief Medical Officer – Canyons Region


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