

<b>DATE:</b>	22 July 2024
<b>TO:</b>	All Clinicians in South Zone and Calgary Zone
<b>FROM:</b>	Molecular Pathology Program, Alberta Precision Laboratories
<b>RE:</b>	<b>Factor V Leiden and Prothrombin G20210A – New Test Method</b>

---

## PLEASE POST OR DISTRIBUTE AS WIDELY AS APPROPRIATE

---

### Key Message

- As of July 22, 2024, all Factor V Leiden and Prothrombin G20210A genetic testing in Calgary will be performed on a new assay methodology with equivalent accuracy, reduced cost and reduced molecular technologist hands-on time. Ordering and result reporting will be unaffected.

### Background

- Factor V Leiden and Prothrombin G20210A testing in the Calgary Diagnostic and Scientific Center (DSC) Molecular Pathology Laboratory has to date been performed by a custom laboratory-developed test (LDT) allele-specific polymerase chain reaction (PCR) run on Agilent TapeStation. This methodology is relatively labor-intensive.
- Custom LDT TaqMan genotyping assays for these biomarkers have been validated and in clinical use in Edmonton for several years. This methodology presents opportunities to reduce costs and technologist time required for the assay while standardizing testing across the province.
- Calgary DSC Molecular Pathology has completed a verification study and will now implement this methodology for clinical testing.

### How this will impact you

- Factor V Leiden and Prothrombin G20210A testing will continue to be ordered and reported in the same way. There will be a change in the Assay Description and Disclaimer on the report reflecting the updated test methodology.

### Action Required

- Ordering Clinicians:** There is no change in specimen acquisition or ordering. Be aware that the report Assay Description and Disclaimer will change; the Results and other sections of the report will not change.

Effective **July 22, 2024**

### Questions/Concerns

- Erik Nohr, Scientific Lead, Molecular Pathology South [erik.nohr@albertaprecisionlabs.ca](mailto:erik.nohr@albertaprecisionlabs.ca)
- Adrian Box, Medical/Scientific Director, Molecular Pathology Program [Adrian.box@albertaprecisionlabs.ca](mailto:Adrian.box@albertaprecisionlabs.ca)

### Approved by

- Dr. Erik Nohr, Acting Medical/Scientific Director, Molecular Pathology Program
- Mark Douesnard, Operations Director, Genetics & Genomics / Molecular Pathology
- Dr. Carolyn O'Hara, Chief Medical Laboratory Officer (Interim), Alberta Precision Laboratories