

TO: ALL CLIENTS  
FROM: LABORATORY REFERENCE CENTRE

JANUARY 18, 2024

## METHODOLOGY CHANGE FOR FACTOR V LEIDEN MUTATION AND PROTHROMBIN GENE MUTATION TESTING

Effective February 1, 2024, the Hamilton Regional Laboratory Medicine Program will be transitioning to a more rapid molecular testing methodology (Cepheid GeneXpert) that simultaneously evaluates for the Factor V Leiden (FVL) Mutation and the Prothrombin Gene Mutation (PGM) (F2, 20210 G-A) associated with thrombophilia. This change is anticipated to result in faster turnaround times. Simultaneous testing for these mutations helps to identify patients at low versus higher risk for thrombosis (see: ***American Society of Hematology 2023 Guidelines for Management of Venous Thromboembolism: Thrombophilia***, PMID: 37195076).

The high risk category includes patients with homozygosity for FVL or combined heterozygosity for FVL and PGM whereas the lower risk category includes heterozygosity for either FVL or PGM.

A pricing change will accompany the methodology change. As of February 1, pricing for the combined FVL/PGM assays will be \$115.00

Please use the HRLMP Molecular Hematology requisition both attached and available online. As the new assay now includes both FVL/PGM, selecting either of them on requisition will result in the test being ordered.

For further assistance please contact:

**Jeffery Cuneo**  
LRC Supervisor  
cuneoj@hhsc.ca  
905-521-2100 x46102

**Jenny Cassano-Campos**  
LRC Customer Support  
cassanocam@hhsc.ca  
905-521-2100 x46103