ALBERTA PRECISION LABORATORIES
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Laboratory Bulletin

DATE:	27 May 2024
TO:	All Hematopathologists and Hematologists in Central Zone, Edmonton Zone and North Zone
FROM:	Molecular Pathology Program, South Sector, Alberta Precision Laboratories
RE:	**Changes to BCR::ABL1 Minor Quantitative Testing in Molecular Pathology South**

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Key Message

- As of May 15, 2024 BCR::ABL1 RT-PCR minor quantitative testing will be transitioned to the Health Canada-approved Asuragen QuantideX qPCR BCR-ABL Minor kit due to recent lack of availability and quality issues with the previously utilized BCR::ABL1 reagents (QIAGEN Ipsogen kits). The new assays detect the same transcript variants as the prior assay with an improved lower limit of transcript detection (log 4.61 reduction / %IS 0.0025%; prior kit, log 3.6 reduction).

Background

- BCR::ABL1 quantitative PCR testing and monitoring is standard clinical care for a subset of patients with ALL. Reduced reagent availability and increased test demand made the transition to a new assay manufacturer necessary. Due to commercial BCR::ABL1 assay standardization, the test performance, reporting changes, and clinical impact will be minimal.

How this will impact you

- Ordering, sample collection, and access to results will be unchanged. Patients may show slight variation in MR/%IS values (less than 0.5 log change) for the 1st sample tested after change-over to the new assay.
- For minor breakpoint detection, the new assay has an improved lower limit of detection of log 4.61 reduction, compared to the prior assay limit of log 3.6. A proportion of patients determined to be “greater than 3.6 log reduction” on the prior assay will therefore demonstrate a specific log reduction value on the new assay.

Action Required

- **Red Deer, Edmonton, and North Zone Oncologists/Hematologists:** There is no change in specimen acquisition or ordering. Results and reporting will be changed to account for the improved limit of detection but all other metrics (%NCN, log reduction, etc) will continue to be reported.

Effective **May 15, 2024**

Questions/Concerns

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Approved by

- Dr. Carolyn O’Hara, Chief Medical Laboratory Officer (Interim), Alberta Precision Laboratories
- Dr. Adrian Box, Medical/Scientific Director, Molecular Pathology Program, APL
- Mark Douesnard, Operations Director, Genetics & Genomics / Molecular Pathology

Effective September 1, 2023, APL has become the sole provider of all public lab services in Alberta. As a result, community lab services formally provided by DynaLIFE Medical Labs will become the responsibility of Alberta Precision Labs (APL). This change impacts all zones.