ALBERTA PRECISION LABORATORIES
Leaders in Laboratory Medicine

Laboratory Bulletin

DATE:	3 May 2024
TO:	All Hematopathologists and Hematologists in Calgary Zone and South Zone
FROM:	Molecular Pathology Program, South Sector, Alberta Precision Laboratories
RE:	**Changes to BCR::ABL1 Quantitative Testing in Calgary Zone and South Zone**

PLEASE POST OR DISTRIBUTE AS WIDELY AS APPROPRIATE

Key Message

- As of May 2, 2024 all BCR::ABL1 RT-PCR quantitative testing (major and minor) will be transitioned to the Health Canada-approved Asuragen QuantideX qPCR BCR-ABL IS kit and Minor kit respectively, 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 assays and are reported as per the International Standard established via IRIS (for major breakpoint). The new major breakpoint assay has a slightly improved lower limit of transcript detection (log 4.7 reduction / %IS 0.002%; prior kit, log 4.5 reduction). The new minor breakpoint assay has 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 patients with CML or a subset of ALL. Testing and reporting are performed using International Scale (White et al., 2010) standardization for major breakpoint quantification. 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

- **Calgary 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 2, 2024**

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Questions/Concerns

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Approved by

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- 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.