Alberta Health Services

# Laboratory Bulletin

**Date:** **February 7, 2013**

**To:** **Central Zone, Edmonton Zone and North Zone**
**Physicians, Nurse Practitioners, Laboratory Directors and Managers**

**From:** **AHS Laboratory Services – Edmonton Zone**
**Molecular Pathology Laboratory – University of Alberta Hospital (UAH)**

**Re:** **Quantitative *BCR-ABL1* Testing**

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**Key Messages:**

- Effective February 11, 2013, the Genetic Laboratory Services (GLS) Molecular Pathology Laboratory at the UAH will begin reporting quantitative *BCR-ABL1* results using the International Scale (IS) for Chronic Myelogenous Leukemia (CML).
- The new assay for *BCR-ABL1* has improved sensitivity.
- Results will be reported in Alberta Netcare under a new test name in the Pathology folder: "**CML BCR-ABL1 IS**", rather than under the name "UAH Molecular Pathology".

**Why this is important:**

- Any specimen collected after January 2, 2013 will be reported in IS units; any specimen collected before this date was reported as a Normalized Copy Number (NCN).
- The IS result and its derived Log Reduction value are more accurate than the NCN and its derived Log Reduction value at clinically relevant thresholds.
- IS results CANNOT be directly compared to older NCN results for monitoring of individual patients. However, the Log Reduction values derived from the IS and NCN are approximately comparable.

**Relevant Information:**

- *BCR-ABL1* levels obtained elsewhere can be compared directly to those reported by the Edmonton Molecular Pathology Laboratory (Genetic Laboratory Services) as long as those results are ALSO reported in IS units.

  **Please note**:

  - Results are only comparable between laboratories when the IS result is <10% (Log Reduction >1).
  - Values >10% (Log Reduction <1) fall into the non-linear range and CANNOT be compared between laboratories.

- The internal control gene used by the Edmonton Molecular Pathology Laboratory is native *ABL1*. The internal control gene often differs between laboratories but does NOT affect the comparability of results when labs report on the IS.

- Results are reported on the International Scale (IS) which is calibrated against the first NIBSC WHO IS standard (ref. 09/138). On this scale 100% is the average value for *BCR-ABL1* levels at initial CML diagnosis; 0.1% is the therapeutic goal at 18 months of therapy termed the Major Molecular Response (MMR). The Log Reduction value is calculated directly from the IS result such that: 100% IS equals 0 Log Reduction, 10% IS equals 1 Log Reduction, 1% IS equals 2 Log Reduction, 0.1% IS equals 3 Log Reduction (MMR), 0.01% IS equals 4 Log Reduction and 0.0032% IS equals 4.5 Log Reduction.

- The change in test name to “CML BCR-ABL1 IS” will also allow clinicians to prepare cumulative *BCR-ABL1* reports and graphs in Alberta Netcare to better track changes over time. However, it should be noted that this feature will only be available for CML. Other diseases associated with *BCR-ABL1*, particularly B-Lymphoblastic Leukemia/Lymphoma will still be reported under the test name UAH Molecular Pathology because the IS scale is only applicable to CML.

**Specimen Requirements:**

- No changes in specimen requirements.

**Inquiries and feedback may be directed to:**

- Dr. Iyare Izevbaye, Head, Molecular Pathology Laboratory, UAH at: 780-407-8025

**This bulletin has been reviewed and approved by:**

Dr. Martin Somerville, Medical / Scientific Director, Genetic Laboratory Services