

January 23, 2020

## HEMATOLOGY

**CHANGE in MOLECULAR TESTING METHODOLOGY for  
QUANTITATION of BCR-ABL1 p210 FUSION TRANSCRIPT****Date effective: February 3, 2020****Background:**

Chronic myeloid leukemia (CML) is a myeloproliferative neoplasm and the standard treatment is targeted tyrosine kinase inhibitor (TKI). The treatment response is usually assessed by a quantitative reverse transcription polymerase chain reaction (qRT-PCR), to detect BCR-ABL1 fusion transcript. Currently Shared Health Molecular Hematopathology laboratory is using a laboratory-developed qRT-PCR method for BCR-ABL1 p210 mRNA quantitation. As of February 3, 2020, the laboratory will switch to a FDA and Health Canada approved methodology - QuantideX® qPCR BCR-ABL IS Kit from Asuragen, Inc. (Austin, TX, USA). The analytic performance characteristics of the new method have been verified in the Molecular Hematopathology laboratory for clinical use.

**Changes in reporting format:**

- The "Normalized Ratio" will be removed from final report.
- A calculated molecular response (MR) will be reported.
- The linear reportable range of the new assay is from 50% IS (MR 0.3) to the 0.002% IS (MR 4.7).
- Positive results with IS (MR) outside of this range will be reported as IS >50% (MR <0.3) or IS <0.002% (MR >4.7).

**Patient impact:**

- Sample requirements remain the same.
- A slight shift of IS score (typically within 0.5 log IS or 0.5 MR) will be expected during the transitional period of method change.
- The new method has a higher sensitivity (IS 0.002% MR 4.7) compared to the current one (IS 0.0032% MR 4.5). Some patients with previously reported negative results may show low positive results (MR close to 4.7) using the new assay.

**References:**

1. Baccarani M, et al. European LeukemiaNet recommendations for the management of chronic myeloid leukemia: 2013. *Blood* 2013, 122:872-884.
2. Asuragen QuantideX® qPCR BCR-ABL IS Kit manual

**More Information:**

For more information for Health Providers, see [Shared Health Clinical Practice Changes](#)

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