VCU Health™

Department of Pathology Laboratories

Notification Date: July 8th, 2025
Effective Date: July 8th, 2025

Implementation of FDA-Approved *BCR::ABL1* Major Quantification Test

Orderable: "BCR-ABL1, Major (p210) Quantitative Blood" test

Effective July 8th, 2025, the Molecular Diagnostics Lab will transition from the Laboratory Developed Test (LDT) to the FDA-approved QuantideX qPCR BCR-ABL IS Kit for *BCR::ABL1* Quantification in peripheral blood samples. The same assay will be used for bone marrow specimens, but as a laboratory-developed test.

Changes to the report:

- The upper limit of the reportable range will change from 66% IS (MR 0.2) to 50% IS (MR 0.3).
- The linear dynamic range of the assay is MR 0.3 to MR 4.7. Positive results below the limit of quantification (LOQ) will be reported as Positive below the limit of quantification (<MR4.7/<0.002%IS). Before, they were reported as Undetectable.
- Epic Chart Review displays the log-converted values of the IS (e.g., 100% IS plotted as 2.00 and 0.1% IS as -1.00). Undetectable and positive below LOQ results are plotted as -2.99.

EPIC impact:

- Specimen stability change: Specimens must be received in the lab within 72 hs of collection (before it was 48 hs).
- Test order remains the same.

For questions, please contact Pathology Client Services at (804) 828-7284 or the Molecular Diagnostics Laboratory at (804) 828-9564.