

Update Methodology for *BCR::ABL1* Minor Quantification Test, effective August 13th, 2025.

Orderable tests (remain the same):

- BCR-ABL1, Minor (p190), Quantitative Blood
- BCR-ABL1, Minor (p190), Quantitative Bone Marrow

Changes to the report:

- The reporting of *BCR::ABL1* minor transcript levels will change from number of cells containing minor p190 per 100,000 total cells to a percentage ratio, specifically the ***BCR::ABL1* to *ABL1* ratio**.

To convert these results to a value that could be comparable to the % ratio for the current assay, use a conversion factor of 1000 (Log 3). For example, a result of 1000 cells in the previous assay would be 1% in the current assay. Similarly, a result of 4 cells would be 0.004%.

- Linear dynamic range = from 25% to 0.0036% ratio.
 - Lower limit of quantitation (LOQ) = 0.0036% ratio.
 - Lower limit of detection (LOD) = 0.0025% ratio.
- Patients with levels of transcript within the linear range will be reported as POSITIVE with the calculated ratio value.
- Patients with levels of transcript less than the LOQ and higher than the LOD will be reported as POSITIVE.
- Patients with very low *BCR::ABL1* signal (less than 0.0025% ratio) or undetected signal will be reported as UNDETECTED.
- Epic Chart Review displays the log-converted values of the ratio, for example:
 - Positive results with 20% ratio are plotted as 1.30 log
 - Ratios above the upper limit of 25% are plotted as 1.40 log
 - Undetectable results are plotted as -4.00 log

EPIC impact:

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

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