Penn Medicine

TO: UPHS Physicians and Staff

FROM: Department of Pathology and Laboratory Medicine
Division of Precision and Computational Diagnostics (PCD)
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SUBJECT: Availability of *BCR-ABL1* quantitative p190 testing

In the middle of March, *BCR-ABL1* quantitative p190 testing will become available from the clinical laboratories at the Hospital of the University of Pennsylvania. This new quantitative test only detects the e1a2 fusion transcript that arises from the minor (p190) breakpoint cluster region. Please note that quantitative testing for the fusion transcripts that arises from the major (p210) breakpoint cluster region (i.e., b2a2 and b3a2 transcripts) will continue to be available as a separately orderable test.

Clinical Significance and Testing Indications

BCR-ABL1 fusion transcript that arises from the minor (p190) breakpoint are predominantly seen in patients with acute lymphoblastic leukemia (ALL); however, the p190 fusion may also be present in a subset of patients with chronic myelogenous leukemia (CML) and even more rarely in acute myeloid leukemia (AML). This quantitative assay is intended for disease monitoring and not for diagnostic purposes.

Results and Reporting:

In comparison to *BCR-ABL1* quantitative p210 studies, there is greater variability in the reporting of *BCR-ABL1* quantitative p190 results. While the majority of laboratories report Normalized Copy Numbers (*e.g.*, *BCR-ABL1* p190 copies/*ABL1* copies), the data are not always reported in the same manner. Some laboratories, including our current reference lab, report a raw ratio (*e.g.*, 0.00096) while others will report the ratio as a percentage (*e.g.*, raw ratio x 100% = 0.096%). To be more consistent with the reporting framework established for *BCR-ABL1* quantitative p210 studies, results from the Hospital of the University of Pennsylvania will be reported as a percent ratio for p190 (*i.e.*, p190 %Ratio). Of note, a standardized reporting scale has not been established for *BCR-ABL1* p190 methods. Furthermore, unlike for p210, a definitive diagnostic reference point and clinically significant milestones (such as the definition of MMR in p210 CML) have not been officially established for p190 measurements. Given this, log reduction values will not be reported for *BCR-ABL1* p190 quantitative studies. Additionally, caution is advised in comparing p190 quantitative results from different laboratories that may report values on a different scale and utilize different testing methodology. For example, the absolute value of a HUP result (reported as p190 %Ratio) will be approximately 25 to 50 times higher than the absolute value of the ARUP result (reported as a raw ratio). Finally, diagnostic samples evaluated by the HUP p190 method will typically to have a result above the upper limit of quantification of the assay (i.e., high positive, above 25%). The linear reportable range for the assay is 25%Ratio to 0.0036%Ratio. Refer to the table below for a summary of the reporting structure:

Overall Result	p190 %Ratio
High Positive, unable to quantify	Above 25
Positive	Value
Low positive, unable to quantify	< 0.0036
Not Detected	Not Detected

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Testing Information
Turnaround Time: 7 business days

Acceptable specimen: The recommended sample types are peripheral blood and bone marrow aspirate.

Ordering: The name of the orderable in PennChart is "BCR-ABL1 QUANTITATIVE (P190)" (PxCode CASEP190). The name of the PennChart orderable for BCR-ABL1 qualitative testing with reflex to quantitative testing is "BCR-ABL1 QUAL to QUANT (P210 and P190)" (PxCode C2008460).

Contact Information: Call the Molecular Pathology Laboratory (215-662-6121) weekdays during regular business hours. For information on ordering and specimen requirements, kindly consult the Lab Tests Services Guide