



To: UPHS Physicians and Staff
 From: The Division of Precision and Computational Diagnostics (PCD)
 Vivianna Van Deerlin, M.D., Ph.D., Director, Molecular Pathology Laboratory
 Christopher Watt, M.D., Ph.D., Associate Director, Molecular Pathology Laboratory
 Jacquelyn Roth, Ph.D., Assistant Professor, Molecular Pathology Laboratory
 Date: September 20th, 2021
 Re: METHOD CHANGE: Qualitative *BCR/ABL1* Testing

In September 2021 the methodology for qualitative *BCR/ABL1* testing is changing which will affect the both the Leukemia Translocation Panel (*RUNX/RUNX1T1*, *CBFB/MYH11*, *PML/RARA*, and *BCR/ABL1*) and the stand-alone *BCR/ABL1* qualitative assay. The new *BCR/ABL1* qualitative assay is intended as a diagnostic methodology wherein samples that are positive for a *BCR/ABL1* fusion will be reflexed and monitored using the *BCR/ABL1* quantitative assays. Assay changes are summarized in the table below:

	Qualitative <i>BCR/ABL1</i> Testing	
	Current Methodology	New Methodology
Result Type	Qualitative detection	No Change
Breakpoints Detected	e13a2 (b2a2) e14a2 (b3a2) e1a2	No Change*
Breakpoints Distinguished	Yes	Yes
Sensitivity (limit of detection)	Approximately 10 ⁻⁴	Approximately 10 ⁻³
Turnaround Time	7 business days	No Change
Urgent <i>BCR/ABL1</i> Testing	FISH, followed by qualitative PCR confirmation for breakpoint	No Change

*Rare fusions may not be detectable with the new methodology. Contact the lab for options to monitor rare *BCR/ABL1* fusion transcripts.

EPIC Ordering – SPHEME order for Molecular Lab	Target	Specimen Type	Typical Usage
BCR-ABL1 t(9;22) RT-PCR – Qualitative MDCML	<i>BCR/ABL1</i>	Bone Marrow	Diagnostic
Acute Leukemia Rearrangement Panel	Full Panel	Bone Marrow	Diagnostic
BCR-ABL1 P210 RT-PCR - Quantitative	<i>BCR/ABL1</i>	Bone Marrow	MRD
BCR-ABL1 P190 RT-PCR - Quantitative	<i>BCR/ABL1</i>	Bone Marrow	MRD

EPIC Ordering	Target	Specimen Type	Typical Usage
BCR-ABL1 QUAL to QUANT (p210 and p190) (PxCode C2008460)	<i>BCR/ABL1</i>	Blood	Diagnostic
Leukemia Translocation Panel (PxCode C2008660)	Full Panel	Blood	Diagnostic
BCR-ABL1 QUANTITATIVE (P210) (PxCode C2008465)	<i>BCR/ABL1</i>	Blood	MRD
BCR-ABL1 QUANTITATIVE (P190) (PxCode CASEP190)	<i>BCR/ABL1</i>	Blood	MRD

Contact Information: Call the Molecular Pathology Laboratory (215-615-3094) weekdays during regular business hours. For information on ordering and specimen requirements, kindly consult the [Lab Tests Services Guide](#).