

To: UPHS Physicians and Staff
 From: The Division of Precision and Computational Diagnostics (PCD)
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 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 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](#).