

This document provides a general product overview of the Bloodhound ABL1 Resistance Panel. Additional information can be found on Precipio's website at [www.precipiodx.com](http://www.precipiodx.com), and the associated IFU (Instructions For Use), available upon request.

<b>Technology Overview</b>	Bloodhound™ ABL1 Resistance Panel is a proprietary set of RUO (Research Use Only) reagents used to detect the wild type (Negative) from Mutated (Positive) genes in a simplified workflow relative to alternative molecular testing technologies (RT-PCR or NGS).
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<b>ABL1</b>	Bloodhound ABL1 Resistance Panel Reagents detect mutations in five different exons of the ABL1 gene, exon 4, exon 5, exon 6, exon 7, and exon 8. Reagents are to be used in conjunction with Bloodhound BCR::ABL1 Quantitative Reagents, for all specimens with detected BCR::ABL1 fusion. The presence of ABL1 mutation can be associated with diagnosis, therapeutic monitoring, detection of minimal residual disease (MRD), therapeutic selection for response to TKIs, and/or stem cell transplantation.
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ABL1 Exons	Coverage			
Exon 4	c.730A>G; p.M244V	c.742C>G; p.L248V	c.749G>A; p.G250E	
	c.757T>C; p.Y253H	c.763G>A; p.E255K	c.764A>T; p.E255V	
Exon 5	c.895G>A; p.V299L		c.895G>T; p.V299L	
Exon 6	c.943A>G; p.T315A	c.949T>G; p.F317V	c.951C>G; p.F317L	c.1075T>G; p.F359V
	c.944C>T; p.T315I	c.949T>A; p.F317I	c.951C>A; p.F317L	c.1075T>A; p.F359I
	c.949T>C; p.F317L	c.950T>G; p.F317C	c.1052T>C; p.M351T	c.1076T>G; p.F359C
Exon 7	c.1187A>G; p.H396R			
Exon 8	c.1375G>A; p.E459K			

<b>Results</b>	The results from Bloodhound ABL1 Resistance Panel are qualitative and DNA sequencing is required to identify specific point mutations.
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<b>Associated WHO/NCCN Guidelines<sup>1</sup></b>	It is estimated that over <a href="#">25% of CML</a> patients will switch TKIs at least once during their lifetime due to TKI intolerance or resistance. <a href="#">Mutations in the kinase domain</a> (KD) of BCR-ABL1 are the most extensively studied mechanism of TKI resistance in CML, but fail to explain anywhere from <a href="#">20–40% of resistant cases</a> .
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	Specificity	Sensitivity	LOD	Storage
<b>Assay Specifications</b>	>99%	98%	2%	-20 °C

SKU	Product Configuration	Assay Contents			
BH-3P-ABL1	3 sample pre-plated plate	Primers/MasterMix Mix	Positive controls	NTC	Wild Type
BH-6P-ABL1	6 sample pre-plated plate	Primers/MasterMix Mix	Positive controls	NTC	Wild Type
BH-20R-ABL1	20 sample free-flow reagents	Primers/MasterMix Mix	Positive controls		

<b>Instrument Required</b>	HRM-enabled RT-PCR (example ThermoFisher Quantstudio 3 or higher)
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<b>Contact</b>	For further questions, contact our technical support team at <a href="mailto:techsupport@precipiodx.com">techsupport@precipiodx.com</a> or call 203-787-7888
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<b>Disclaimer</b>	<i>The information in this document represents the company's best understanding of the technical and regulatory landscape; however, it should not serve as any guidance to any laboratory seeking to implement HemeScreen. Laboratory managers and medical directors should seek their own information independently through their CLIA inspector and any other state and federal regulatory body available.</i>
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