

This document provides a general product overview of the BloodHound AML Assay. Additional information can be found on Precipio's website at www.precipiodx.com, and the associated IFU (Instructions For Use), available upon request.

Technology Overview	BloodHound® is a proprietary set of RUO (Research Use Only) reagents used to screen the wild type (Negative) from Mutated (Positive) genes in a simplified workflow relative to alternative molecular testing technologies (RT-PCR or NGS).
AML Assay	Acute myeloid leukemia (AML) is a clonal malignant neoplasm of myeloid cell lineage involving the blood and bone marrow, but other tissue can also be occasionally affected. In the era of personalized precision medicine, molecular changes have been used in AML classification, diagnosis, prognosis, risk stratification, and treatment.

Genes Tested	Coverage
KIT Exon 8	c.1504_1509dup; p.A502_Y503dup
IDH1 Exon 4	p.R100, p.G105, p.R132
IDH2 Exon 4	p.R140, p.R172
FLT3 Exon 14	Internal Tandem Duplications
FLT3 Exon 15	Internal Tandem Duplications
FLT3 Exon 16	Internal Tandem Duplications
FLT3 Exon 20	Mutations in codons 835 and 836
NPM1 Exon 12	Type A, Type B, Type D

Results	The results from BloodHound® AML are qualitative and DNA sequencing is required to identify specific isoforms.
Associated WHO/NCCN Guidelines	In Acute Myeloid Leukemia (AML), every hour matters. Current WHO disease classification and NCCN Clinical Practice Guidelines emphasize comprehensive molecular testing at diagnosis to identify actionable mutations that influence diagnosis, prognostic risk stratification, targeted therapy selection, and disease monitoring. Comprehensive molecular profiling—including FLT3, IDH1, IDH2, NPM1, and KIT—is now considered an essential component of the initial AML workup. (PMC) https://pubmed.ncbi.nlm.nih.gov/40630561/

Assay Specifications	Specificity	Sensitivity	LOD
	>99%	95%	5%

SKU	Product Name	Assay Contents			
HS-1P-AML	1 sample pre-plated plate	Primers/MasterMix Mix	Positive controls	NTC	Wild Type
HS-20R-AML	20-sample free-flow reagents	Primers/MasterMix Mix	Positive controls		

Storage	-20 °C
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Machine Required	HRM-enabled RT-PCR (example ThermoFisher Quantstudio 3 or higher)
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Contact	For further questions, contact our technical support team at techsupport@precipiodx.com or call 203-787-7888
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Disclaimer	<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 BloodHound. 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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