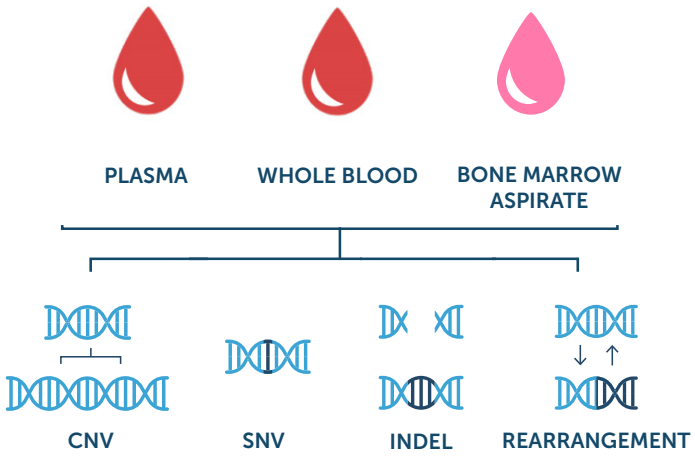
PredicineHEME™

CLIA Validated NGS Assay for Hematologic Malignancies

Highly sensitive NGS assay designed to predict responses to immunotherapies and targeted therapies for blood cancers

Methods and Reporting

- Detects single nucleotide variants (SNVs), insertions and deletions (indels), copy number variations (CNVs), and DNA rearrangements
- Detects critical biomarkers in B-cell malignancies, including chronic lymphocytic leukemia/small lymphocytic lymphoma (CLL/ALL) and mantle cell lymphoma (MCL)
- Multiple sample types acceptable for testing, including whole blood, plasma, and bone marrow aspirate



PERFORMANCE SPECIFICATIONS			
	Allele Frequency/Copy Number	Sensitivity	Positive Predictive Value (PPV)
Single Nucleotide Variations	0.3% MAF	99.4%	100%
Indels	0.3% MAF	100%	100%
DNA Rearrangements	0.3% MAF	100%	100%
Copy Number Gain*	2.23 copies	100%	100%
Regions Analyzed	1.1 Mb		
Sequencing	Illumina NGS		
Turnaround Time	10 days		
Target Sequence Coverage	20,000x		
Specimen Type and Requirement	4 ml plasma 1 tube of whole blood 0.4 ml bone marrow aspirate		

*Copy Number Gain is for Research Use Only (RUO)

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