

PredicineHEME™

106-Gene cfDNA Assay for Hematologic Malignancies

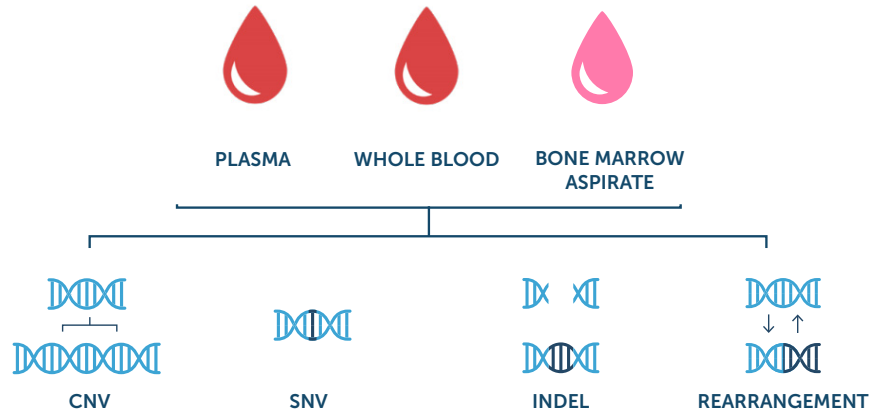
Highly sensitive cfDNA assay designed to predict responses to immunotherapies and targeted therapies for blood cancers

106

Key cancer genes interrogated

≥0.05%

Limit of detection (LOD)



Methods and Reporting

- Detects Single Nucleotide Variants (SNVs), Indels, Copy Number Variations (CNVs), and rearrangement
- Measures critical biomarkers in B-cell malignancies including chronic lymphocytic leukemia/small lymphocytic lymphoma (CLL/SLL) and mantle cell lymphoma (MCL)
- Multiple sample types acceptable for testing
- Test results are provided in a report with clinically relevant genomic findings listed
- Research Use Only (RUO)

Workflow



Gene List & Performance Specifications

ACTN2	AKT1	ALK	ARID1A	ARID1B	ASXL1	ATM	B2M
BAX	BCL2	BCL2L1	BCL6	BCORL1	BIRC3	BMI1	BRAF
BTK	CARD11	CCND1	CCND2	CCND3	CD274 (PD-L1)	CD38	CD79A
CD79B	CDK2	CDK4	CDKN1B	CDKN2A	CDKN2B	CHEK2	CREBBP
CXCR4	DDX3X	DNMT3A	EP300	ERBB3	EZH2	FBXW7	FOXO1
GNAS	GPS2	HRAS	IGH	IGK	IGL	IL10RA	IRF2BP2
IRF4	ITGA4	JAK1	JAK2	JAK3	KMT2C	KMT2D (MLL2)	KRAS
MALT1	MAP2K1	MAP3K14	MAPK1	MCL1	MEF2B	MKI67	MYC
MYD88	NFKB1	NFKB2	NOTCH1	NOTCH2	NOTCH3	NRAS	NSD2
PDCD1	PIK3CA	PIK3CD	PIK3R1	PIM1	PIM2	PLCG1	PLCG2
PPM1D	PTEN	PTPN11	RB1	RPS15	S1PR1	SETD2	SF3B1
SLC16A1	SLC16A5	SOX11	STAT1	STAT2	STAT3	STAT5B	STAT6
TERT _{promoter}	TET2	TLR2	TNFAIP3	TNFRSF13C	TNFRSF1A	TP53	TRAF2
TRAF3	XPO1						

SNVs + Indels
 CNVs
 Fusions
 Fusions + CNVs

PERFORMANCE SPECIFICATIONS				
	Reportable Range	Allele Frequency/Copy Number	Sensitivity	Positive Predictive Value (PPV)
Single Nucleotide Variations	≥0.05%	≥0.5% AF	100%	100%
		0.25-0.5% AF	97.9%	99.2%
		0.1% AF	42.5%	94.4%
Indels	≥0.05%	≥0.5% AF	100%	100%
		0.25-0.5% AF	100%	100%
		0.1% AF	40%	100%
DNA Re-arrangements	≥0.05%	≥0.375% AF	100%	100%
		0.25% AF	100%	100%
		0.1% AF	60%	100%
Copy Number Gain	≥2.18	≥2.375 copies	100%	100%
		2.23 copies	100%	100%
Regions Analyzed	610 kb			
Sequencing and Bioinformatics	Illumina NGS			
Assay Sensitivity	0.25% report down to 0.05%			
Turnaround Time	10 days			
Target Sequence Coverage	20,000x			
Specimen Type and Requirement	4ml plasma 1 tube of whole blood 0.4ml bone marrow aspirate			

PredicineHEME™ is a research use only assay.