

PredicineHEMETM

106-gene cfDNA Assay for Hematologic Malignancies

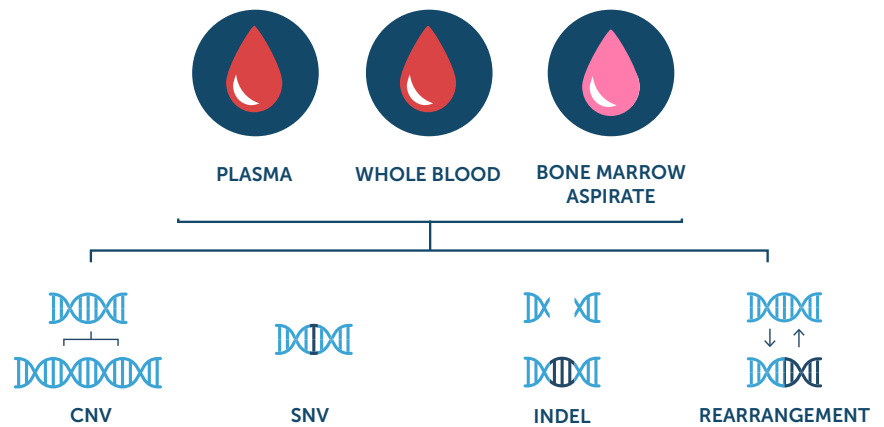
Highly sensitive cfDNA assay designed to predict responses to immunotherapies and targeted therapies for blood cancers

106

Key cancer genes interrogated

$\geq 0.05\%$

Limit of detection



Methods and Reporting

- Detects SNVs, Indels, 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 an interpretive report with clinically relevant genomic findings listed

Workflow



Gene List

| | | | | | | | |
|--------------------------|---------|---------|---------|-----------|---------------|--------------|---------|
| 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.