Hematologic Malignancy Panel

TEST NAME: HEMATOLOGIC MALIGNANCY PANEL

TEST CODE: HMPLBL; HMPLBM

(ORDER HMPLBL FOR WHOLE BLOOD SAMPLES, HMPLBM FOR BONE MARROW SAMPLES)

CPT CODE: 81455

CLINICAL USE:
Cancer driver alterations in the oncogenes and tumor suppressor genes cause dysregulation of signaling pathways and cellular processes controlling the proliferation, migration, metabolism, and apoptosis. Identification of these genetic alterations in the tumors is essential in the diagnosis, prognosis, and treatment of cancers. This panel sequences 94 genes that are involved in hematologic malignancies.

The genes covered in our 94 gene panel are listed below.

ABL1	CALR	CSF1R	FOXP1	JAK2	MYBL2	PLCG2	SH2B3	TNFRSF14
AKT1	CARD11	CSF3R	GATA1	JAK3	NF1	PRDM1	SMC1A	TP53
ARNTL	CBL	CUX1	GATA2	KDM6A	NOTCH1	PRMT5	SMC3	U2AF1
ASXL1	CBLB	DNMT3A	GNA13	KIF17	NOTCH2	PTEN	SOCS1	WHSC1
ATM	CCND1	EP300	HNRNPK	KIT	NOTCH3	PTPN11	SRSF2	WT1
BCL2	CD79B	ETV6	HRAS	KLHL6	NPM1	PTPRD	STAG2	ZRSR2
BCL6	CDKN2A	EZH2	IDH1	KMT2C	NRAS	PTPRT	STAT3	
BCOR	CEBPA	FAM5C	IDH2	KMT2D	PAX5	RAD21	SUZ12	
BIRC3	CLSTN1	FBXW7	IKZF1	KRAS	PHF6	RUNX1	TCF3	
BRAF	CREBBP	FLT3	IL7R	MEF2B	PIAS2	SETBP1	TET2	
BTK	CRLF2	FOXO1	JAK1	MPL	PIK3R2	SF3B1	TNFAIP3	

METHODOLOGY: DNA is extracted and hybridized with custom-designed probes to enrich the targeted regions of 94 genes associated with hematologic malignancies. Samples are then sequenced on the Illumina HiSeq 2500 (Illumina, Inc, CA). A custom bioinformatics pipeline aligns the data to human reference genome GRCh37 to call variants. The limit of detection (related in part to depth of coverage, neoplastic cell percentage, and allelic frequency for the mutation) was determined to be 5% allele frequency, at which our assay has sensitivity of 98% and 94%, respectively, to detect single nucleotide variants (SNVs) and insertions/deletions (indels). Mutant allele populations below this detection limit will not be reliably detected by this method. Pseudogenes, highly homologous regions, and repeat regions may interfere with the detection of variants in this assay. This assay targets genes involved in hematologic malignancies. Some of the genes targeted may also cause inherited genetic disorders, variants in these genes will not be reported unless they are determined to contribute to the diagnosis, prognosis, or treatment of hematologic malignancies.

COMPONENTS:

REFERENCE RANGE: NA

SPECIMEN REQUIREMENTS:

- 2-4 mL of blood or bone marrow-purple (EDTA) tube or yellow (ACD) tube. Minimum 1 mL.
- DNA 10 µg at a minimum of 100 ng/µL.

SPECIAL HANDLING: NA

TEST PERFORMANCE SCHEDULE: Weekly

TURN AROUND TIME: 2-3 Weeks

STAT AVAILABILITY: NA

REFERENCES:

1. Papaemmanuil et al. Genomic Classification and Prognosis in Acute Myeloid Leukemia. The New England Journal of Medicine. 2016, 374;23: 2209-2221
2. Sperling et al. The genetics of myelodysplastic syndrome: from clonal haematopoiesis to secondary leukaemia. Nature Reviews, Cancer. Jan 2017, 17: 5-19.