MEDPACE

NGS CANCER PANEL SERVICES

Clinical laboratories worldwide are implementing next-generation sequencing (NGS) to identify cancer genomic variants and ultimately improve patient outcomes. The cancer panel is the test used in analyzing multiple genes at once for cancer-associated variants. Depending on the included genes, cancer panels can either be broad in scope or targeted towards specific cancer types. These cancer types include, but are not limited to, lung, ovarian, prostate, breast, brain, gastrointestinal, and colorectal cancer. The Medpace NGS cancer panel is designed to detect variants including single nucleotide variants (SNVs) and insertions/deletions (indels) from both full-length genomic DNA extracted from whole blood or FFPE tissue and cell-free DNA extracted from plasma and covers all the cancer types mentioned above.

TEST DETAILS

The Medpace cancer panel target regions include part or full exonic sequences (including the immediate flanking intronic boundaries) of the 82 proto-oncogenes and tumor suppressor genes listed in table 1 and oncogenic hotspots genes, as well as some deeper intronic and promoter regions with diagnostic or prognostic association with tumor malignancies. The panel utilizes KAPA HyperPETE Panel probes designed to provide high capture efficiency, sequencing uniformity with less optimization and higher variant detection confidence. Sequencing is performed on the Illumina NextSeq 550, which uses sequencing-by-synthesis (SBS) technology to perform cluster generation and next-generation sequencing from enriched DNA libraries.

ABL1	CCND2	EZH2	IDH1	MSH2	NTRK3	RHOA
AKT1	CCNE1	FBXW7	IDH2	MSH6	PDGFRA	RIT1
ALK	CDH1	FGFR1	JAK2	MTOR	PIK3CA	SMAD4
APC	CDK12	FGFR2	JAK3	MYC	PMS2	SMO
AR	CDK4	FGFR3	KIT	MYCN	PTEN	STK11
ARID1A	CDK6	GATA3	KRAS	NF1	PTPN11	TERT
ATRX	CDKN2A	GNA11	MAPK1	NF2	RAD51C	TP53
BRAF	CIC	GNAQ	MAPK3	NFE2L2	RAD51D	TSC1
BRCA1	DDR2	GNAS	MDM2	NOTCH1	RAF1	TSC2
BRCA2	EGFR	H3F3A	MET	NPM1	RB1	VHL
BRIP1	ERBB2	HNF1A	MLH1	NRAS	RET	
CCND1	ESR1	HRAS	MPL	NTRK1	RHEB	

Table 1. List of cancer genes included in the MRL Cancer gene panel.

SPECIMEN TYPES

Formalin-fixed paraffine-embedded tissue (FFPE) blocks or slides, whole blood collected in K2-EDTA tubes for genomic DNA extraction, and plasma for cell free DNA (cfDNA) extraction. To maintain cfDNA integrity during blood collection and storage, it's recommended to collect whole blood in Streck BCT tubes or Paxgene cfDNA tubes.

SENSITIVITY, SPECIFICITY AND LIMIT OF DETECTION (LOD)

The overall sensitivity of the assay with cfDNA > 97.92% (for VAFs ranging from 0.5% to 92.5%), and with FFPE samples >95.65% (for VAFs ranging from 1% to 92.5%).

The specificity of the assay with cfDNA: 100%, and with FFPE samples 92.86%.

The LoD for the assay is set to 0.5% VAF as the minimum with sensitivity evaluated as 97.92% at this VAF.

REPORTABLE OUTCOME

Variants will be interpreted and classified into one of the following categories based on the AMP/ASCP/CAP Standards and Guidelines for the Interpretation and Reporting of Sequence Variants in Cancer: Tier I (variants of strong clinical significance), Tier II (variants of potential clinical significance), Tier III (variants of unknown clinical significance), and Tier IV (benign or likely benign variants). Tier IV variants will not be reported.

REFERENCE RANGE

Each gene targeted in this assay has an associated wildtype reference sequence. The references used in this assay are based on the Genome Reference Consortium GRCh38 build and established gene reference sequences (RefSeqs).

NGS AT MEDPACE

Medpace uses several Illumina-based NGS instruments including the MiSeqDx, NextSeq 550 and NextSeq 2000 at both our US and Belgium laboratories. Medpace is capable of performing several NGS techniques including Whole genome sequencing (WGS), Whole exome sequencing (WES), RNA-sequencing (RNA-seq) and targeted gene sequencing. Our validated Targeted sequencing panels include a Cancer panel, Familial Hypercholesterolemia (FH) panel, a Myeloid Malignancies panel and a dyslipidemia panel. Targeted panels have the advantage of providing increased depth of coverage while generating sequencing information in a cost-effective manner.

FULL-SERVICE CLINICAL DEVELOPMENT

Medpace is a scientifically driven, global, full-service clinical contract research organization (CRO) providing Phase I-IV clinical development services to the biotechnology, pharmaceutical and medical device industries. Medpace's mission is to accelerate the global development of safe and effective medical therapeutics through its high science and disciplined operating approach that leverages local regulatory and deep therapeutic expertise across all major areas including oncology, cardiology, metabolic disease, endocrinology, central nervous system and anti-viral and anti-infective.