PredicineCARE™

CLIA Validated cfDNA NGS Assay

Predicine

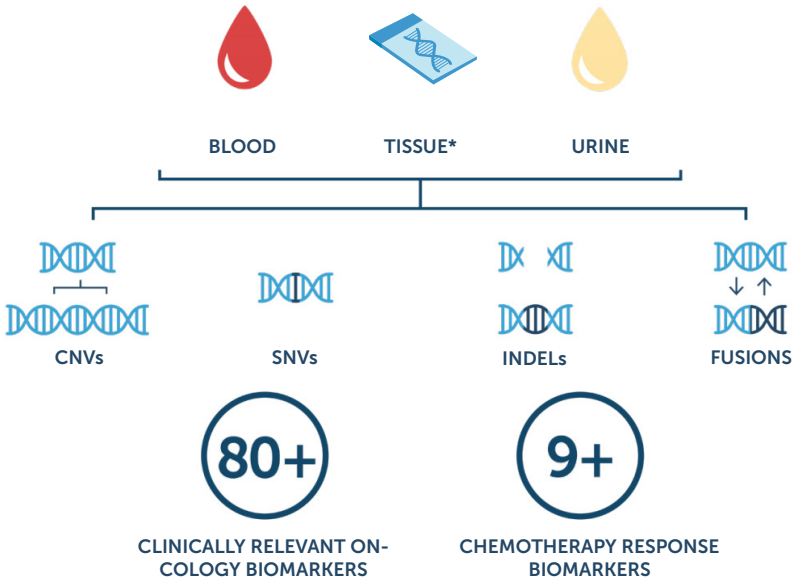
Pan-cancer NGS assay that detects genomic alterations to inform patient care and clinical trials in targeted therapy

152

Key cancer genes interrogated

20,000x

Sequencing Depth

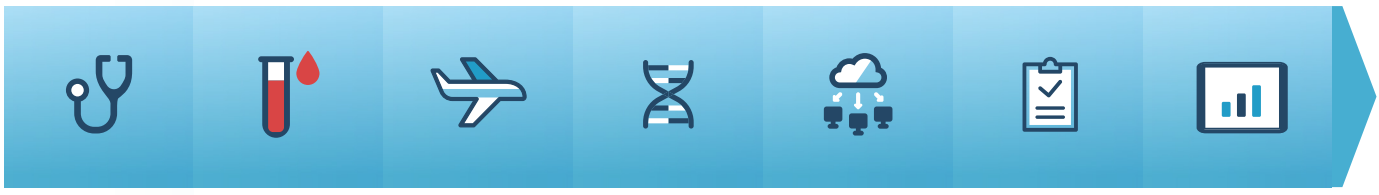


* Product is for Research Use Only (RUO)

Methods and Reporting

- Identifies four main classes of genomic alterations: single-nucleotide variants (SNVs), indels, copy number variations (CNVs), fusions
- Covers cancer-related genomic alteration relevant for clinical drug development
- Test results are provided in an interpretive report with clinically relevant genomic findings

Workflow



Predicine, Inc. | (650) 300-2188 | contact@predicine.com | www.predicine.com

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Gene List & Performance Specifications

PredicineCARE™ interrogates 152 key genes

ABRAXAS1	AKT1	AKT2	AKT3	ALK	APC	AR	ARAF	ARID1A	ATM
ATRX	BAP1	BARD1	BCL2	BRAF	BRCA1	BRCA2	BRIP1	BTK	CCND1
CCND2	CCND3	CCNE1	CCNE2	CD274 (PD-L1)	CD74	CDH1	CDK12	CDK2	CDK4
CDK6	CDKN2A	CHEK1	CHEK2	CTNNB1	CXCR4	CYP2C19	CYP2D6	CYP3A4	DAXX
DDR2	DPYD	E2F1	EGFR	EPCAM	ERBB2 (HER2)	ERBB3	ERCC1	ESR1	EZH2
FANCA	FANCC	FANCF	FANCG	FANCL	FAT1	FBXW7	FEN1	FGFR1	FGFR2
FGFR3	FGFR4	FLT3	FOXA1	FOXL2	FZR1	GEN1	GNA11	GNAQ	GNAS
GSTP1	HNF1A	HOXB13	HRAS	IDH1	IDH2	JAK2	JAK3	KDM6A	KIT
KMT2C	KMT2D (MLL2)	KRAS	MAP2K1 (MEK1)	MAP2K2 (MEK2)	MAPK1	MAPK3	MDM2	MET	MLH1
MPL	MRE11	MSH2	MSH6	MTHFR	MTOR	MYC	MYCN	MYD88	NBN
NF1	NFE2L2	NOTCH1	NPM1	NRAS	NTRK1	NTRK2	NTRK3	PALB2	PDCD1LG2 (PD-L2)
PDGFRA	PIK3CA	PIK3CB	PIK3R1	PLCG2	PMS2	POLD1	POLE	PPP2R1A	PRKACA
PRKD1	PTEN	PTPN11	RAD50	RAD51	RAD51B	RAD51C	RAD51D	RAD52	RAF1
RB1	RET	RHEB	RHOA	RIT1	RNF43	ROS1	SDHB	SMAD4	SMO
SPOP	STAG2	STK11	TERT promoter	TMPRSS2	TP53	TSC1	TSC2	UGT1A1	VHL
XPC	XRCC1								

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	98.6%	99.2%
		<0.25% AF	78.3%	97.9%
Indels	≥0.05%	≥0.5% AF	100%	100%
		0.25% - 0.5% AF	98.6%	100%
		<0.25% AF	80%	100%
Re-arrangement	≥0.05%	≥0.5% AF	100%	100%
		0.375 - 0.5% AF	96.7%	100%
		0.25% - 0.375% AF	90%	100%
		<0.25% AF	33.3%	100%
Copy Number Gain	≥2.18	≥2.375 copies	100%	100%
		2.23 - 2.375 copies	100%	100%
		<2.23 copies	45%	81.8%
Copy Number Loss	≤1.85	≤1.75 copies	100%	100%
		1.75 - 1.80 copies	93.6%	91.7%
		1.80 - 1.85 copies	66%	88.6%
Sequencing and Bioinformatics	Illumina NGS			
Turnaround Time	10 days			
Target Sequence Coverage	20,000x for biofluid, 2,000x for tissue			

Specimen Type and Requirement		CLIA	RUO
	Liquid biopsy (blood)	8 mL plasma 2 tubes of whole blood	2-4 mL plasma 1 tube of whole blood
	Liquid biopsy (urine)	20-40 mL urine	40 mL urine
	Tissue biopsy	Not applicable	2-10 FFPE slides