PredicineCARE™

CLIA Validated NGS Assay

Predicine

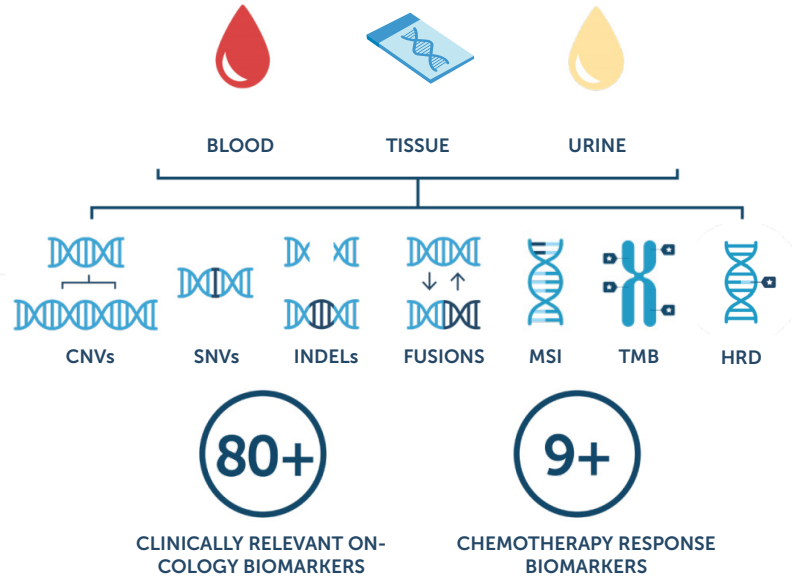
Pan-cancer NGS assay that detects genomic alterations to inform patient care and clinical trials in targeted therapy

152

Key cancer genes interrogated

20,000x

Sequencing Depth (Liquid Biopsy)



Methods and Reporting

- Identifies main classes of genomic alterations: single-nucleotide variants (SNVs), indels, copy number variations (CNVs), fusions, microsatellite instability (MSI) and tumor mutational burden (TMB) and homologous recombination deficiency (HRD)
- Covers cancer-related genomic alterations relevant for clinical drug development
- Test results are provided in an interpretive report with clinically relevant genomic findings

Workflow

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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

	Plasma				Urine			
Variant Type	Reportable Range	Allele Frequency/ Copy Number	Sensitivity	Positive Predictive Value (PPV)	Reportable Range	Allele Frequency/ Copy Number	Sensitivity	Positive Predictive Value (PPV)
Single Nucleotide Variations	≥0.05%	0.375% AF	100%	98.4%	≥0.1%	0.5% AF	99.1%	99.4%
		0.25% AF	95.8%	99.10%		0.3% AF	95.4%	97.6%
		0.1% AF	78.3%	97.9%		0.1% AF	92.7%	100%
Indels	≥0.05%	0.375% AF	100%	100%	≥0.1%	0.5% AF	100%	100%
		0.25% AF	95.7%	100%		0.3% AF	96.2%	100%
		0.1% AF	80.0%	100%		0.1% AF	91.7%	100%
DNA Re-arrangement	≥0.05%	0.375% AF	96.7%	100%	≥0.1%	0.5% AF	100%	100%
		0.25% AF	90.0%	100%		0.3% AF	98.0%	100%
		0.1% AF	33.3%	100%		0.1% AF	26.7%	100%
Copy Number Gain	≥2.18	2.23-2.37 copies	100%	100%	≥2.20	2.20-2.32 copies	100%	100%
Copy Number Loss	≤1.85	≤1.75 copies	100%	100%				

Biomarker [Plasma Sample]	Tumor Fraction	Sensitivity
Homologous Recombination Deficiency (HRD)	25% TF	100%
	20% TF	100%
	15% TF	100%
	10% TF	22.2%

Sequencing	Illumina NGS		
Turnaround Time	6 days - Urine and Plasma	10 days - Tissue	
Target Sequence Coverage	20,000x for biofluid, 2,000x for tissue		
Specimen Type and Requirement		CLIA	RUO
	Liquid biopsy (blood)	20 mL blood	2-5 mL plasma 4-10 mL blood
	Liquid biopsy (urine)	20-40 mL urine	20-40 mL urine
	Tissue Biopsy	≥ 1mm^3 tissue (5-10 FFPE slides)	≥ 1mm^3 tissue (5-10 FFPE slides)