PredicineCARE™

Now CE Marked

152 Gene CLIA-certified cfDNA Liquid Biopsy Panel

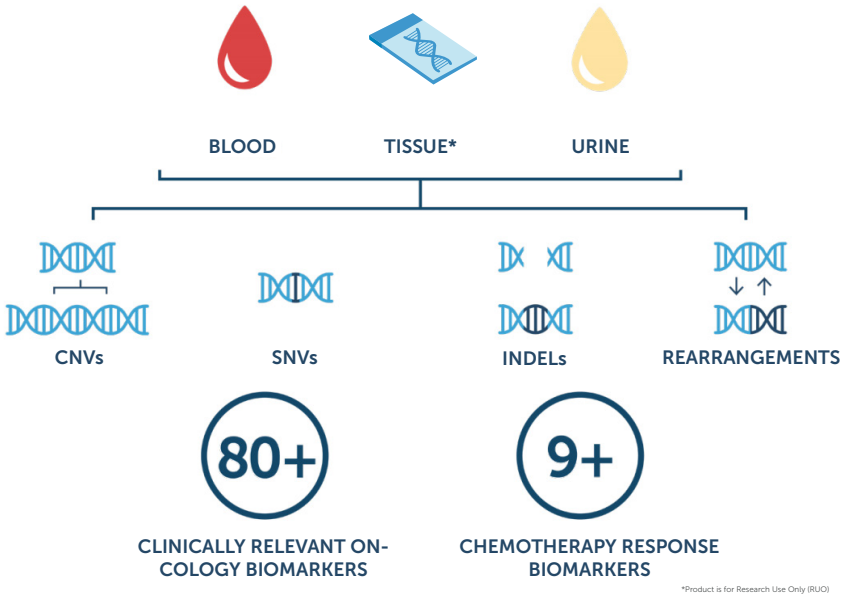
Pan-cancer liquid biopsy assay that detects clinically actionable genes to inform patient care and clinical trials in targeted therapy

152

Key cancer genes interrogated

20,000x

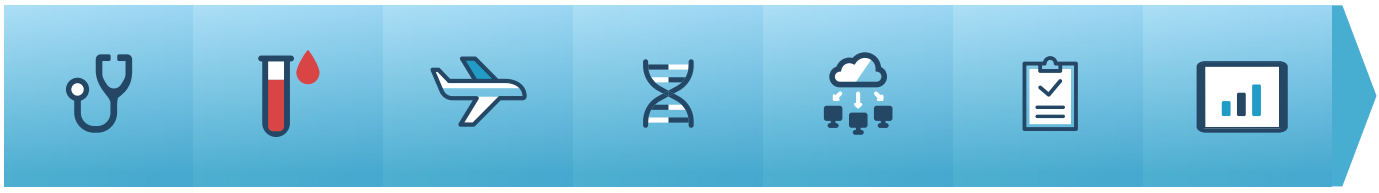
Sequencing Depth



Methods and Reporting

- Identifies four main classes of genomic alterations: Single-Nucleotide Variants (SNVs), Indels, Copy Number Amplification (CNA), Copy Number of Reduction (CNR), Fusions
- Covers all guideline recommended targetable alterations across patient care and clinical drug development from targeted therapies to immunotherapies
- Test results are provided in an interpretive report with clinically relevant genomic findings listed

Workflow



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Gene List & Performance Specifications

PredicineCARE™ interrogates 152 genes, including 103 genes with complete exonic coverage and 49 genes with select exonic coverage (indicated with *).

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%
		≤1.85 copies	66%	88.6%
Regions Analyzed & Panel Size	152 genes, 582 kb			
Sequencing and Bioinformatics	Illumina NGS			
Assay Sensitivity	0.25% report down to 0.05%			
Turnaround Time	10 days			
Target Sequence Coverage	>20,000x for biofluid, >2,000x for tissue			
Specimen Type and Requirement		CLIA	Research Use Only (RUO)	
	Liquid biopsy (blood)	8 mL plasma 2 tubes of whole blood	2-4 mL plasma 1 tubes of whole blood	
	Liquid biopsy (urine)	40 mL urine	20-40 mL urine	
	Tissue biopsy		2-10 FFPE slides	

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