

# PredicineCARE

152-Gene CLIA-certified cfDNA Liquid Biopsy Panel

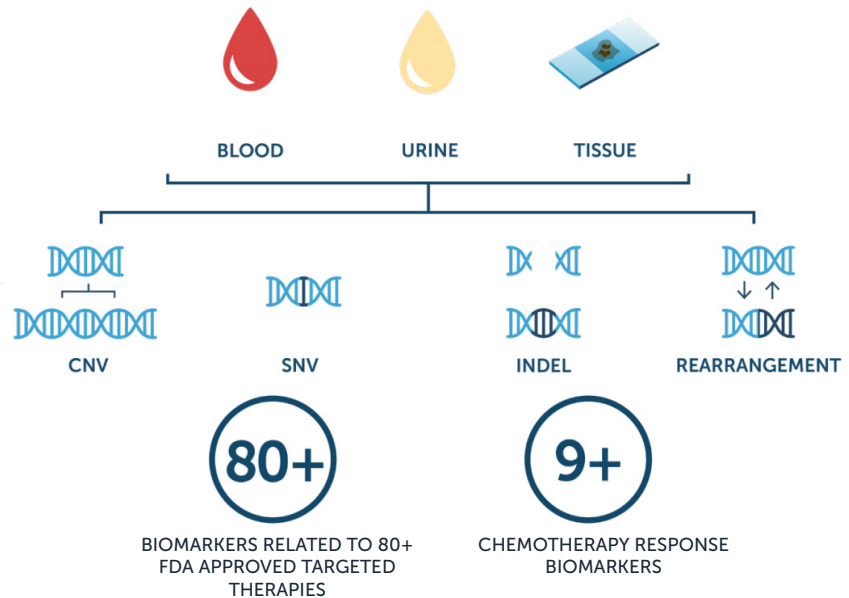
A pan-cancer liquid biopsy test that detects clinically actionable genes to inform patient care and clinical trials in targeted therapy

152

Key cancer genes interrogated

582 kb

Broad genome coverage



## Methods and Reporting

- Identifies four main classes of genomic alterations (base substitutions, insertions and deletions, copy number variations, and re-arrangements) and MSI status
- Covers biomarkers with FDA-approved drugs and emerging biomarkers for clinical applications
- Test results are provided in an interpretive report with clinically relevant genomic findings listed

## Workflow



## Gene List

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 <sub>(PD-L1)</sub>	CD74	CDH1	CDK12	CDK2	CDK4
CDK6	CDKN2A	CHEK1	CHEK2	CTNNB1*	CXCR4	CYP2C19*	CYP2D6*	CYP3A4*	DAXX
DDR2*	DPYD*	E2F1	EGFR	EPCAM*	ERBB2 <sub>(HER2)</sub>	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* <sub>(MLL2)</sub>	KRAS	MAP2K1 <sub>(MEK1)</sub>	MAP2K2 <sub>(MEK2)</sub>	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 <sub>(PD-L2)</sub>
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* <sub>promoter</sub>	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		<b>RUO</b>	<b>CLIA</b>	
	<b>Liquid biopsy</b>	2ml plasma 1 tube of whole blood 40ml urine	8ml plasma 2 tubes of whole blood	
	<b>Tissue biopsy</b>	10 FFPE slides	10 FFPE slides	

## Current Gene List

### Entire coding sequence (base substitutions and indels)

ABRAXAS1	AKT1	AKT2	AKT3	ALK*	APC	AR	ARAF	ARID1A	ATM
ATRX	BAP1	BARD1	BCL2	BRAF	BRCA1	BRCA2	BRIP1	BTK*	CCND1
CCND2*	CCND3	CCNE1*	CD274 (PD-L1)	CDH1	CDK12	CDK4	CDK6	CDKN2A	CHEK1
CHEK2	CTNNB1*	CXCR4	CYP2C19*	CYP2D6*	CYP3A4*	DAXX	DDR2*	DPYD*	EGFR
EPCAM*	ERBB2 (HER2)	ERBB3*	ERCC1	ESR1	EZH2	FANCA	FANCC	FANCF	FANCG
FANCL	FAT1*	FBXW7*	FEN1	FGFR1	FGFR2	FGFR3	FGFR4	FLT3*	FOXA1
FOXL2	GEN1	GNA11	GNAQ	GNAS*	GSTP1*	HNFB1A*	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	TP53
TSC1*	TSC2*	UGT1A1*	VHL	XPC*	XRCC1*				

### CNVs

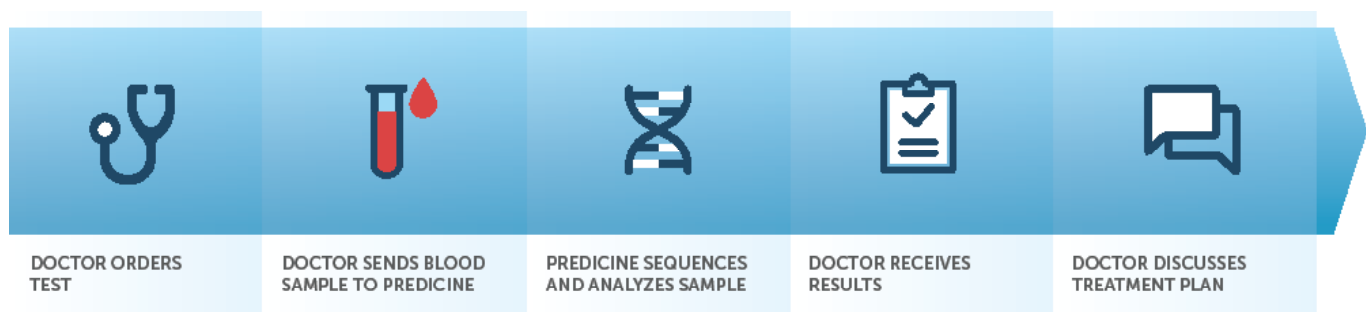
AKT1	AKT2	AKT3	APC	AR	ARID1A	ATM	ATRX	BRAF	BRCA1
BRCA2	CCND1	CCND2	CCND3	CCNE1	CCNE2	CD274	CDK12	CDK2	CDK4
CDK6	CDKN2A	E2F1	EGFR	ERBB2	ERBB3	FAT1	FGFR1	FGFR2	FGFR3
FGFR4	FZR1	GNA11	JAK2	KIT	KRAS	MAP2K2	MDM2	MET	MYC
MYCN	NF1	PALB2	PDCD1LG2	PDGFRA	PIK3CA	POLE	PTEN	RAF1	RB1
ROS1	SMO	TMPRSS2	TP53						

### Fusions

ALK	BRAF	CD274	CD74	EGFR	FGFR1	FGFR2	FGFR3	NTRK1	NTRK2
PDGFRA	PRKACA	RET	ROS1	TMPRSS2					

\*Genes with selected exonic coverage

## Workflow






## Current Gene List

### Genes with full coding exonic regions included in PredicineCARE.

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 <sub>(PD-L1)</sub>	CD74	CDH1	CDK12	CDK2	CDK4
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DDR2*	DPYD*	E2F1	EGFR	EPCAM*	ERBB2 <sub>(HER2)</sub>	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* <sub>(MLL2)</sub>	KRAS	MAP2K1 <sub>(MEK1)</sub>	MAP2K2 <sub>(MEK2)</sub>	MAPK1	MAPK3	MDM2	MET	MLH1
MPL*	MRE11	MSH2	MSH6	MTHFR*	MTOR*	MYC	MYCN	MYD88	NBN
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PDGFRA*	PIK3CA	PIK3CB	PIK3R1	PLCG2*	PMS2	POLD1	POLE	PPP2R1A*	PRKACA*
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XPC*	XRCC1*								

\* Genes with selected exonic coverage

- SNVs + Indels
-  Fusions
-  CNVs
-  Fusions + CNVs

## Methods and Reporting

- Uses a proprietary hybrid capture-based next-generation sequencing methodology combined with in-house proprietary computational algorithms that enable accurate and sensitive detection of cancer variants
- Utilizes proprietary workflow to accurately identify unique cfDNA fragments from blood
- Test results are provided in an interpretive report with clinically relevant genomic findings listed

### PERFORMANCE SPECIFICATION

Specimen Type and Requirement	Liquid biopsy	5ml plasma 20ml whole blood
Turnaround Time	10 days	
Regions Analyzed	152 genes	
Panel Size	582kb	
Sequencing	Illumina NGS	
Assay Sensitivity	0.25% report down to 0.1%	
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