PredicineCARE™

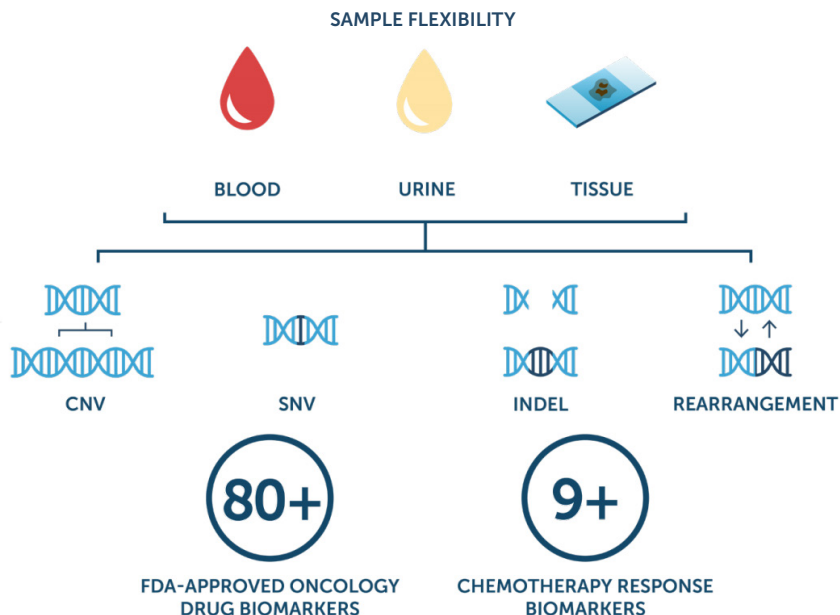## GU Optimized CLIA-certified cfDNA Liquid Biopsy Panel

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

20,000x
2 to 4x greater depth of coverage than most liquid biopsy tests

SAMPLE FLEXIBILITY

BLOOD   URINE   TISSUE

CNV   SNV   INDEL   REARRANGEMENT

80+ FDA-APPROVED ONCOLOGY DRUG BIOMARKERS

9+ CHEMOTHERAPY RESPONSE BIOMARKERS

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

Sample Collection

1 Complete the Test Requisition Form (TRF).

TEST REQUISITION FORM

2 Fill out barcode labels
- Patient ID/Initials
- DOB
- Collection Date

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3 Collect blood as instructed on the collection instruction sheet included with the test kit. Place barcode label on each tube with barcode in the vertical position.

LABEL

4 Place barcode label on the TRF, then fold and insert the TRF into the biohazard bag.

FOLDED FORM

BIOHAZARD BAG

5 Place filled blood tubes into the foam tray.

6 Place filled foam tray into the specimen bag along with the TRF and zip seal the biohazard bag.

BIOHAZARD BAG

Predicine

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 (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

		CLIA	Research Use Only (RUO)
Specimen Type and Requirement	Liquid biopsy	8ml plasma 2 tubes of whole blood	2 ml plasma 1 tubes of whole blood 40ml urine
	Tissue biopsy	10 FFPE slides	10 FFPE slides