

Product Description

Caris Assure® is a laboratory-developed test that provides comprehensive molecular profiling from a single blood sample for patients with advanced solid malignancies.* The test analyzes DNA and RNA from plasma with whole exome (WES) and whole transcriptome sequencing (WTS), respectively, as well as WES of genomic DNA from white blood cells. This approach enables reporting of fusions from both RNA and DNA and distinguishes somatic tumor-derived alterations from incidental germline variants† and clonal hematopoiesis–associated findings, supporting more complete and accurate identification of actionable biomarkers for therapy selection.

Caris Assure detects single nucleotide variants (SNV) and insertions/deletions (INDEL) exome-wide, including genes in cancer pathways, with clinical reporting focused on more than 300 genes associated with cancer therapies, prognosis or etiology. The assay reports clinically significant SNV, INDEL, resistance mechanisms, and select copy number alterations and gene fusions through integrated DNA and RNA analysis. It also reports predicted HLA genotype, the pharmacogenomic markers DPYD and UGT1A1, and the complex genomic signatures microsatellite instability (MSI) and blood tumor mutational burden (bTMB).

Whole Exome and Whole Transcriptome Sequencing from Blood



Technology

Whole Exome Sequencing • Whole Transcriptome Sequencing



Genes & Depth

23,000+ • Up to 40,000x; median 25,000x for Drug-Rule panel



Biological Coverage

Plasma: cfDNA, cfRNA • White Blood Cells: gDNA



Biomarkers (including resistance mutations)

SNV • INDEL • CNA • Fusions/Rearrangements



Variant Source

Tumor-Derived • Incidental Germline† • Clonal Hematopoiesis



Genomic Signatures / Other

bTMB • PGx: DPYD & UGT1A1 • MSI • Predicted HLA Genotype

Intended Use

Caris Assure is intended for patients with previously diagnosed solid malignant neoplasms when tissue is not feasible or when updated molecular information is needed to inform biomarker-associated therapy selection, and is to be used by qualified healthcare professionals. The assay provides a comprehensive, evidence-based molecular profile to help oncologists identify biomarker-associated therapies with potential benefit, recognize therapies with potential lack of benefit, and identify relevant clinical trial opportunities.

Performance Specifications

Reported performance is based on ≥30 ng of cfDNA input using a composite tissue-liquid comparator that incorporates the FDA-approved MI Cancer Seek® tissue assay and the original Caris Assure assay to account for the biology of tumor-derived signals in blood.

Alteration	Limit of Detection	Threshold for Positivity
SNV	Min: 0.09% VF / Median: 0.22% VF	Quality-dependent, ≥3 reads
INDEL	Min: 0.12% VF / Median: 0.20% VF	Quality-dependent, ≥3 reads
CNA	Min: 0.5% TF / Median: 1% TF	≥2.55 copies
DNA Rearrangements	Min: 0.05% VF / Median: 0.33% VF	≥2 reads
RNA Fusions	Min: 0.13% FF / Median: 0.44% FF	≥2 reads

SNV: Single Nucleotide Variant
 INDEL: Insertion or deletion
 CNA: Copy Number Amplification
 VF: Variant Frequency
 TF: Tumor Fraction
 FF: Fusion Frequency

Limit of detection is defined here as the minimum observed VF at the lowest target VF level with a ≥95% hit rate across replicates. Reported SNV and INDEL LOD are for Drug-Rule panel variants. Fusion frequency (FF) is the expression level of ctRNA-derived fusion-supporting reads normalized by that of the housekeeping genes *OAZ1*, *SERF2* and *MPPI*.

Gene List

Caris Assure tests for variants in 23,000+ genes with clinical reporting on more than 300 genes with known clinical associations with cancer therapies, prognosis or etiology. Calculation of blood tumor mutational burden (bTMB) utilizes the entire exome.

SNV & INDEL

ABL1	BLM	CIC	ERCC6	FUBP1	KRAS	NF1	PLCB4	RET	STK11
ACD	BMPRI1A	CNOT3	ERG	GATA3	LZTR1	NF2	PMS2	RHEB	SUFU
ACVR1	BRAF	COL2A1	ESR1	GNA11	MAP2K1	NFE2L2	POLD1	RHOA	SUZ12
ACVR1B	BRCA1	CREBBP	EXT1	GNA13	MAP2K2	NFKBIA	POLE	RIT1	TCF7L2
AIP	BRCA2	CSF1R	EZH2	GNAQ	MAP2K4	NFKBIE	POT1	RNF43	TERT
AJUBA	BRIP1	CSF3R	FANCA	GNAS	MAP3K1	NKX2-1	PPARG	ROS1	TET2
AKT1	BTB	CTCF	FANCB	GRIN2A	MAPK1	NOTCH1	PPM1D	RRAS2	TGFBR1
AKT2	CALR	CTNNA1	FANCC	GRM3	MAX	NOTCH2	PPP2R1A	RUNX1	TGFBR2
AKT3	CARD11	CTNNB1	FANCD2	H3F3A	MDH2	NOTCH3	PPP2R2A	SDHA	TMEM127
ALK	CASP8	CUL3	FANCE	H3F3B	MDM2	NPM1	PPP6C	SDHAF2	TNFAIP3
AMER1	CBFB	CXCR4	FANCF	HIST1H3B	MED12	NRAS	PRDM1	SDHB	TNFRSF14
AR	CBL	CYLD	FANCG	HNFI1A	MEF2B	NRG1	PREX2	SDHC	TP53
APC	CCDC6	CYSLTR2	FANCI	HOXB13	MEN1	NSD1	PRKACA	SDHD	TRAF3
ARAF	CCND1	DACH1	FANCL	HRAS	MET	NSD2	PRKAR1A	SETD2	TRAF7
ARHGAP35	CCNE1	DDR2	FANCM	IDH1	MGA	NT5C2	PRKD1	SF3B1	TRIM28
ARID1A	CCND2	DGCR8	FAS	IDH2	MITF	NTHL1	PRKDC	SMAD2	TERRAP
ARID2	CCND3	DICER1	FAT1	IGF1R	MLH1	NTRK1	PTCH1	SMAD4	TSC1
ASXL1	CD274	DNMT3A	FBXW7	IRF4	MLH3	NTRK2	PTEN	SMARCA2	TSC2
ATM	CD79B	DPYD	FGF3	JAK1	MPL	NTRK3	PTPN11	SMARCA4	U2AF1
ATP6AP1	CDC73	EED	FGF4	JAK2	MRE11	NYNRIN	PTPRD	SMARCB1	UGT1A1
ATP6AP2	CDH1	EGFR	FGFR1	JAK3	MSH2	PALB2	RABL3	SMARCE1	VHL
ATR	CDK12	EIF1AX	FGFR2	KBTBD4	MSH3	PARP1	RAC1	SMO	WRN
ATRX	CDK4	ELF3	FGFR3	KDM5C	MSH6	PBRM1	RAD50	SOCS1	WT1
AXIN1	CDK6	ELOC	FGFR4	KDM6A	MTAP	PDGFRA	RAD51B	SOS1	XPO1
AXIN2	CDKN1A	EP300	FH	KDR	MTOR	PDGFRB	RAD51C	SOX9	XRCC1
B2M	CDKN1B	EPHA2	FLCN	KEAP1	MUTYH	PHOX2B	RAD51D	SPEN	
BAP1	CDKN2A	ERBB2	FLT1	KIT	MYC	PIK3CA	RAD54L	SPOP	
BARD1	CDKN2B	ERBB3	FLT3	KLF4	MYCN	PIK3CB	RAF1	SRC	
BCL2	CEBPA	ERBB4	FLT4	KMT2D	MYD88	PIK3R1	RASA1	STAG2	
BCL9	CHEK1	ERCC2	FOXA1	KMT2A	MYOD1	PIK3R2	RB1	STAT3	
BCOR	CHEK2	ERCC5	FOXL2	KMT2C	NBN	PIM1	RBM10	STAT5B	

DNA Rearrangements

ALK	BRAF	ERG	FGFR1	FGFR2	FGFR3	NRG1	NTRK1	NTRK2	NTRK3	RET	ROS1
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RNA Fusions

ALK	BRAF	ERG	FGFR1	FGFR2	FGFR3	NRG1	NTRK1	NTRK2	NTRK3	RET	ROS1
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Gene List

Caris Assure tests for variants in 23,000+ genes with clinical reporting on more than 300 genes with known clinical associations with cancer therapies, prognosis or etiology. Calculation of blood tumor mutational burden (bTMB) utilizes the entire exome.

Copy Number Amplification

<i>AKT3</i>	<i>CD274</i>	<i>ERBB2</i>	<i>FGFR2</i>	<i>KRAS</i>	<i>MYC</i>	<i>NRAS</i>	<i>NTRK3</i>	<i>PPARG</i>	<i>TYMS</i>
<i>ALK</i>	<i>CDK4</i>	<i>ERBB3</i>	<i>FGFR3</i>	<i>MDM2</i>	<i>MYCL</i>	<i>NSD3</i>	<i>PDGFRA</i>	<i>TAZ1</i>	<i>YAP1</i>
<i>BRAF</i>	<i>CDK6</i>	<i>ESR1</i>	<i>HRAS</i>	<i>MET</i>	<i>MYCN</i>	<i>NTRK1</i>	<i>PIK3CA</i>	<i>TFEB</i>	<i>YES1</i>
<i>CCNE1</i>	<i>EGFR</i>	<i>FGFR1</i>	<i>KIT</i>	<i>MYB</i>	<i>NECTIN4</i>	<i>NTRK2</i>	<i>PLAG1</i>	<i>TOP1</i>	

Copy Number Deletions

<i>ARID1A</i>	<i>BRCA1</i>	<i>CDKN2A</i>	<i>FANCL</i>	<i>MLH1</i>	<i>NFE2L2</i>	<i>RAD51D</i>	<i>SDHD</i>	<i>TSC1</i>	
<i>ATM</i>	<i>BRCA2</i>	<i>CDKN2B</i>	<i>FH</i>	<i>MRE11</i>	<i>PALB2</i>	<i>RAD54L</i>	<i>SMARCA4</i>	<i>TSC2</i>	
<i>ATR</i>	<i>BRIP1</i>	<i>CHEK1</i>	<i>JAK1</i>	<i>MTAP</i>	<i>PTEN</i>	<i>SDHA</i>	<i>SMARCB1</i>	<i>VHL</i>	
<i>BAP1</i>	<i>CD274</i>	<i>CHEK2</i>	<i>JAK2</i>	<i>NBN</i>	<i>RAD51B</i>	<i>SDHB</i>	<i>SMO</i>		
<i>BARD1</i>	<i>CDK12</i>	<i>FANCA</i>	<i>KEAP1</i>	<i>NF1</i>	<i>RAD51C</i>	<i>SDHC</i>	<i>STK11</i>		

Incidental Germline†

<i>AIP</i>	<i>BMPR1A</i>	<i>CDKN1B</i>	<i>FLCN</i>	<i>MITF</i>	<i>NF1</i>	<i>POLE</i>	<i>RB1</i>	<i>SMAD4</i>	<i>TP53</i>
<i>ALK</i>	<i>BRCA1</i>	<i>CDKN2A</i>	<i>HOXB13</i>	<i>MLH1</i>	<i>NF2</i>	<i>POT1</i>	<i>RET</i>	<i>SMARCA4</i>	<i>TSC1</i>
<i>APC</i>	<i>BRCA2</i>	<i>CHEK2</i>	<i>KIT</i>	<i>MSH2</i>	<i>NTHL1</i>	<i>PRKAR1A</i>	<i>SDHA</i>	<i>SMARCB1</i>	<i>TSC2</i>
<i>ATM</i>	<i>BRIP1</i>	<i>CTNNA1</i>	<i>LZTR1</i>	<i>MSH3</i>	<i>PALB2</i>	<i>PTCH1</i>	<i>SDHAF2</i>	<i>SMARCE1</i>	<i>VHL</i>
<i>AXIN2</i>	<i>CDC73</i>	<i>DICER1</i>	<i>MAX</i>	<i>MSH6</i>	<i>PDGFRA</i>	<i>PTEN</i>	<i>SDHB</i>	<i>STK11</i>	<i>WT1</i>
<i>BAP1</i>	<i>CDH1</i>	<i>EGFR</i>	<i>MEN1</i>	<i>MTAP</i>	<i>PMS2</i>	<i>RAD51C</i>	<i>SDHC</i>	<i>SUFU</i>	
<i>BARD1</i>	<i>CDK4</i>	<i>FH</i>	<i>MET</i>	<i>MUTYH</i>	<i>POLD1</i>	<i>RAD51D</i>	<i>SDHD</i>	<i>TMEM127</i>	

*Caris Assure is intended for patients with previously diagnosed solid malignant neoplasms when tissue profiling is not feasible and is to be used by qualified healthcare professionals. Not available in all locations.

†Not a replacement for comprehensive germline testing. Incidental pathogenic alterations are reported, including ACMG-recognized cancer genes. Negative results do not imply the patient does not harbor a germline mutation.