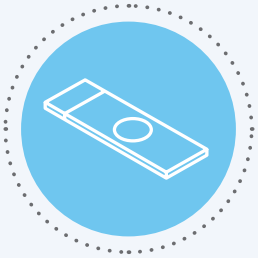
Comprehensive Molecular Profiling
Tumor Tissue or Whole Blood

Caris Life Sciences® performs comprehensive molecular profiling to assess biomarkers in both tissue and blood, helping to guide more precise and individualized treatment decisions for cancer patients.

TISSUE-BASED MOLECULAR PROFILING – MI Tumor Seek Hybrid™



DNA
Whole Exome Sequencing
SNVs, Indels, CNAs, Karyotyping, Viruses

RNA
Whole Transcriptome Sequencing
Gene Fusions, Gene Expression and Variant Transcripts

AVAILABLE WITH MI PROFILE™

Protein
Immunohistochemistry
Tumor-Relevant Protein Biomarkers

Caris GPSai™
Cancer type similarity assessment intended to help identify the tumor of origin by comparing molecular characteristics of the patient's tumor against 90 tumor categories in the Caris database.

Caris FOLFIRSTai™
Chemotherapy response predictor intended to gauge a mCRC patient's likelihood of benefit from first-line FOLFOX+BV followed by FOLFIRI+BV, versus FOLFIRI+BV followed by FOLFOX+BV treatment.

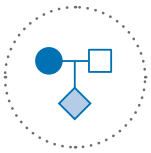
BLOOD-BASED MOLECULAR PROFILING – Caris Assure™

FROM PLASMA

Somatic Tumor
Tumor-derived mutations

BUFFY COAT FROM WHITE BLOOD CELLS

Incidental Clonal Hematopoiesis (CH)
Non-tumor mutations (false-positives)



Incidental Germline
Hereditary variants

Shipper kits for specimen transportation to our lab is an important part of the molecular profiling process. Shipper kits and requisitions can be ordered on-demand via QR code.

MI Profile™ Comprehensive Testing (Tissue)

MI Tumor Seek Hybrid™ + IHCs and Other Tests by Tumor Type. Tissue-based Whole Exome and Whole Transcriptome Sequencing analysis, plus additional tumor-type relevant biomarker testing (IHC, ISH, etc.). Caris FOLFIRSTai™ is performed for mCRC cases and Caris GPSai™ is performed for CUP cases.

Biological Coverage
(DNA) SNVs, InDels, CNAs, Karyotyping, Viruses
(RNA) Gene Fusions, Gene Expression and Variant Transcripts
(Protein) 15+ Tumor-specific antigens

Variant Coverage
Somatic Tumor

Technologies
NGS IHC PyroSeq CISH

Next-Generation Sequencing
Whole Exome (DNA) Whole Transcriptome (RNA)

Genes & Depth
23,000+ 1500x

Genomic Signatures/Other
gLOH HRD MSI TMB HLA Genotype

Specimen Quantity
20% Tumor (NGS) | 10 slides (NGS only) 25 slides (NGS+IHC)

Clinical AI
Caris FOLFIRSTai™ Caris GPSai™

Viruses
HPV 16 & 18 (Head & Neck, Anal, Genital, CUP)

EBV (Head & Neck, Esophagogastric Junction, Gastric Adenocarcinoma, CUP. If positive result in cancer type not listed here, EBER ISH reflex to confirm EBV result)

MCPyV (Merkel Cell, Neuroendocrine – Poorly Differentiated (High-Grade)/Large or Small Cell Carcinoma, CUP)

Chromosomal Alterations
+7/-10 and 1p19q co-deletion (glioma)

Additional tumor-type relevant biomarker testing:

Tumor Type	Immunohistochemistry (IHC)	Other
Bladder	Her2/Neu, PD-L1 (22c3)	
Breast	AR, ER, Her2/Neu, PD-L1 (22c3), PR, PTEN	
Cancer of Unknown Primary – Female	AR, ER, Her2/Neu, PD-L1 (SP142)	
Cancer of Unknown Primary – Male	AR, Her2/Neu, PD-L1 (SP142)	
Cervical	Her2/Neu, PD-L1 (22c3)	
Cholangiocarcinoma/ Hepatobiliary	Her2/Neu, PD-L1 (SP142)	
Colorectal and Small Intestinal	Her2/Neu, MMR, PD-L1 (SP142)	
Endometrial (all except uterine sarcoma)	ER, Her2/Neu, MMR, PD-L1 (SP142), PR	
Esophageal Cancer	Her2/Neu, PD-L1 (22c3)	
Gastric/GEJ	CLDN18, Her2/Neu, MMR, PD-L1 (22c3)	*EBER* (Chromogenic *in situ* Hybridization)
GIST	Her2/Neu, PD-L1 (SP142)	
Glioma	Her2/Neu	*MGMT* Methylation (Pyrosequencing)
Head & Neck	Her2/Neu, p16, PD-L1 (22c3)	*EBER*, HPV (Chromogenic *in situ* Hybridization), HPV reflex to confirm p16 result
Kidney	Her2/Neu, PD-L1 (SP142)	

Tumor Type	Immunohistochemistry (IHC)	Other
Melanoma	Her2/Neu, PD-L1 (SP142)	
Merkel Cell	Her2/Neu, PD-L1 (SP142)	
Neuroendocrine	Her2/Neu, PD-L1 (SP142)	
Non-Small Cell Lung	ALK*, Her2/Neu, MET*, PD-L1 (22c3, 28-8, SP142, SP263)	
Ovarian	ER, FOLR1†, Her2/Neu†, PD-L1 (22c3), PR	
Pancreatic	Her2/Neu, PD-L1 (SP142)	
Prostate	AR, Her2/Neu, PD-L1 (SP142)	
Salivary Gland	AR, Her2/Neu, PD-L1 (SP142)	
Sarcoma	Her2/Neu, PD-L1 (SP142)	
Small Cell Lung	Her2/Neu, PD-L1 (22c3)	
Thyroid	Her2/Neu, PD-L1 (SP142)	
Uterine Sarcoma	ER, Her2/Neu, MMR, PD-L1 (SP142), PR	
Vulvar Cancer (SCC)	Her2/Neu, PD-L1 (22c3)	
Other Tumors	Her2/Neu, PD-L1 (SP142)	

MMR = Mismatch Repair proteins: MLH1, MSH2, MSH6, PMS2
**ALK IHC and MET IHC only performed for NSCLC adenocarcinoma.*
†FOLR1 IHC and HRD Status only performed for epithelial ovarian cancer.
Availability of certain assays and features may vary by location. Check website for complete details.

MI Tumor Seek Hybrid™ (Tissue)

Tissue-based Whole Exome and Whole Transcriptome Sequencing analysis. Caris FOLFIRSTai™ is performed for mCRC cases and Caris GPSai™ is performed for CUP cases.

Biological Coverage
(DNA) SNVs, InDels, CNAs, Karyotyping, Viruses
(RNA) Gene Fusions, Gene Expression and Variant Transcripts

Variant Coverage
Somatic Tumor

Technologies
NGS

Next-Generation Sequencing
Whole Exome (DNA) Whole Transcriptome (RNA)

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Chromosomal Alterations
+7/-10 and 1p19q co-deletion (glioma)

Caris Assure™ (Blood)

Blood-based Whole Exome and Whole Transcriptome Sequencing for pathogenic and likely pathogenic tumor-derived, incidental germline, and incidental CH variant detection.

Technology
Circulating Nucleic Acids Sequencing (cNAS)

Application
Biomarker Analysis
(including resistance mutations)

Biological Coverage
Plasma: cfDNA, cfRNA
White Blood Cells: gDNA, mRNA

Variant Coverage (pathogenic and likely pathogenic)
Somatic Tumor-Derived
Incidental Germline‡
Incidental CH

Genes & Depth
23,000+
8,000x (raw average for clinically relevant genes)

Next-Generation Sequencing
Whole Exome
Whole Transcriptome

Alterations
SNV INDEL CNA Fusions

Genomic Signatures / Other
bTMB MSI HLA Genotype

Sample Quantity
2 Tubes Whole Blood

Performance in Advanced/Metastatic Patients
Compared to matched tissue collected within 30 days; based on ≥5 ng of cNAS input. Minimum reportable allele frequency is 0.1%.

Clinically Actionable SNV and INDEL:
Sensitivity 93.8% PPV 96.8%
Specificity >99.9%

Incidental Germline‡:
Sensitivity >99% PPV >99%
Specificity >99%

‡*Not a replacement for comprehensive germline testing. Incidental pathogenic alterations detected in ACMG recognized cancer genes and others are reported. Negative results do not imply the patient does not harbor a germline mutation.*

Caris Assure™ is intended for patients with previously diagnosed solid malignant neoplasms when tissue is not feasible and is to be used by qualified healthcare professionals. RNA results are intended for investigational purposes only. Not available in all locations. Check website for complete details.

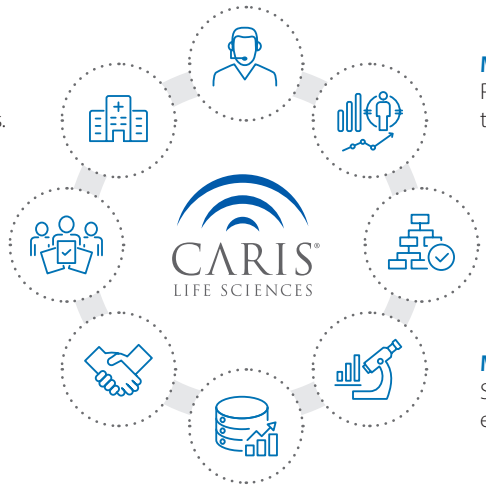
Comprehensive Support

Caris is committed to providing the highest quality of support for physicians and patients. A dedicated multifunctional local team provides a wide range of support including case management, continuing education, investigator-led research support and assistance with molecular tumor boards.

Account Management
Coordinates case management, site training, logistics, online ordering/portal needs.

Strategic Accounts Management
Partners with senior leaders for broader, system-wide projects and contracting needs.

Molecular Oncology Specialists
Provides product updates and information, testing capabilities and issue management.



Customer Support
Facilitates case setup, ordering support (kits, questions), patient billing information, etc.

Precision Medicine Initiatives Team
Assists with technical lab workflows and efficiencies.

Account Implementation Team
Collaborates with hospital administration and laboratory for service agreements and contracting needs.

Molecular Science Liaisons (MDs/PhDs)
Supports technical, scientific and medical educational needs for precision medicine.

Precision Oncology Program Team
Implements EHR integrations and other electronic ordering and reporting initiatives.

Caris Molecular Testing – Complete Gene Coverage

As the pioneer in precision medicine, Caris was the first to provide WES and WTS for every patient. All molecular profiling orders include next-generation sequencing of 23,000+ genes. Listed below are the genes most commonly associated with cancer. Full gene search is available on CarisLifeSciences.com.

ABL1	*BCR*	*CSF1R*	*FANCC*	*GNAQ*	*LZTR1*	*MUTYH*	*PIK3CB*	*RAD51D*	*SOCS1*
ABL	*BLM*	*CTNNA1*	*FANCD2*	*GNAS*	*MAML2*	*MYB*	*PIK3R1*	*RAD54L*	*SPEN*
ACVR1	*BMPR1A*	*CTNNB1*	*FANCE*	*H3F3A*	*MAP2K1*	*MYC*	*PIK3R2*	*RAF1*	*SPOP*
AIP	*BRAF*	*CXCR4*	*FANCF*	*H3F3B*	*MAP2K2*	*MYCN*	*PIM1*	*RASA1*	*SRC*
AKT1	*BRCA1*	*CYLD*	*FANCG*	*HDAC1*	*MAP2K4*	*MYD88*	*PKN1*	*RB1*	*SSBP1*
AKT2	*BRCA2*	*CYP17A1*	*FANCI*	*HIST1H3B*	*MAP3K1*	*NBN*	*PMS1*	*RELA*	*STAG2*
AKT3	*BRD3*	*DDR2*	*FANCL*	*HIST1H3C*	*MAPK1*	*NF1*	*PMS2*	*RET*	*STAT3*
ALK	*BRD4*	*DICER1*	*FANCM*	*HNF1A*	*MAPK3*	*NF2*	*POLD1*	*RHOA*	*STK11*
AMER1	*BRIP1*	*DNMT3A*	*FAS*	*HOXB13*	*MAST1*	*NFE2L2*	*POLD2*	*RNF43*	*SUFU*
APC	*BTK*	*EGFR*	*FAT1*	*HRAS*	*MAST2*	*NFKBIA*	*POLD3*	*ROS1*	*TERT*
AR	*CALR*	*EGFR vIII*	*FBXW7*	*IDH1*	*MAX*	*NOTCH1*	*POLD4*	*RPA1*	*TET2*
ARAF	*CARD11*	*EGLN1*	*FGFR1*	*IDH2*	*MED12*	*NOTCH2*	*POLE*	*RPA2*	*TFE3*
ARHGAP26	*CASP8*	*ELF3*	*FGFR2*	*INSR*	*MEF2B*	*NPM1*	*POLQ*	*RPA3*	*TFEB*
ARHGAP35	*CBFB*	*EP300*	*FGFR3*	*IRF4*	*MEN1*	*NRAS*	*POT1*	*RPA4*	*THADA*
ARID1A	*CCND1*	*EPHA2*	*FGFR4*	*JAK1*	*MET*	*NRG1*	*PPARG*	*RSPO2*	*TMEM127*
ARID2	*CCND2*	*ERBB2*	*FGR*	*JAK2*	*MET Exon 14 Skipping*	*NSD1*	*PPP2R1A*	*RSPO3*	*TMPRSS2*
AR-V7	*CCND3*	*ERBB3*	*FH*	*JAK3*	*MGA*	*NTHL1*	*PPP2R2A*	*RUNX1*	*TNFAIP3*
ASXL1	*CD274*	*ERBB4*	*FLCN*	*KDM5C*	*MGMT*	*NTRK1*	*PRDM1*	*SDHA*	*TNFRSF14*
ATM	*CD79B*	*ERCC2*	*FLT1*	*KDM6A*	*MITF*	*NTRK2*	*PRKACA*	*SDHAF2*	*TP53*
ATR	*CDC73*	*ERG*	*FLT3*	*KDR*	*MLH1*	*NTRK3*	*PRKAR1A*	*SDHB*	*TRAF7*
ATRX	*CDH1*	*ESR1*	*FLT4*	*KEAP1*	*MLH3*	*NUMBL*	*PRKCA*	*SDHC*	*TSC1*
AXIN1	*CDK12*	*ETV1*	*FOXA1*	*KIF1B*	*MPL*	*NUTM1*	*PRKCB*	*SDHD*	*TSC2*
AXIN2	*CDK4*	*ETV4*	*FOXL2*	*KIT*	*MRE11*	*PALB2*	*PTCH1*	*SETD2*	*U2AF*
AXL	*CDK6*	*ETV5*	*FUBP1*	*KLF4*	*MSH2*	*PARP1*	*PTEN*	*SF3B1*	*VHL*
B2M	*CDKN1B*	*ETV6*	*FYN*	*KMT2A*	*MSH3*	*PBRM1*	*PTPN11*	*SMAD2*	*WRN*
BAP1	*CDKN2A*	*EWSR1*	*GALNT12*	*KMT2C*	*MSH6*	*PCNA*	*RABL3*	*SMAD4*	*WT1*
BARD1	*CHEK1*	*EXO1*	*GATA3*	*KMT2D*	*MSMB*	*PDGFRA*	*RAC1*	*SMARCA4*	*XPO1*
BCL2	*CHEK2*	*EZH2*	*GLI2*	*KRAS*	*MST1R*	*PDGFRB*	*RAD50*	*SMARCB1*	*XRCC1*
BCL9	*CIC*	*FANCA*	*GNA11*	*LCK*	*MTOR*	*PHOX2B*	*RAD51B*	*SMARCE1*	*XRCC2*
BCOR	*CREBBP*	*FANCB*	*GNA13*	*LYN*	*MUSK*	*PIK3CA*	*RAD51C*	*SMO*	*YES1*

Availability of certain assays and features may vary by location. Check website for complete details.

To order or learn more, visit **www.CarisLifeSciences.com.**
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