

# Comprehensive Molecular Profiling

## New York State



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

### MI PROFILE™ COMPREHENSIVE TESTING



#### DNA

##### Whole Exome Sequencing

SNVs, Indels, CNAs, Karyotyping, Viruses



#### RNA

##### Whole Transcriptome Sequencing

Gene Fusions, Gene Expression and Variant Transcripts



#### Protein

##### Immunohistochemistry

Tumor-Relevant Protein Biomarkers

Caris GPSai™ is performed for CUP cases and Caris FOLFIRSTai™ is performed for mCRC cases.

### MI TUMOR SEEK HYBRID™ (Next-Generation Sequencing Only)



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Caris GPSai™ is performed for CUP cases and Caris FOLFIRSTai™ is performed for mCRC cases.

### AI-BASED SIGNATURES

Caris GPSai™ is performed for CUP cases and can be added to any solid tumor order by selecting the appropriate box on the Caris requisition form. Caris FOLFIRSTai™ is performed for all mCRC cases.

#### 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.



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 [www.CarisLifeSciences.com/request-supplies](http://www.CarisLifeSciences.com/request-supplies) (QR code).





# MI Profile™ Comprehensive Testing

**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

## Technologies

NGS IHC PyroSeq CISH

## Next-Generation Sequencing

Whole Exome (DNA) Whole Transcriptome (RNA)

## Genes & Depth (DNA) | Reads (RNA)

23,000+ 1500x | 17 Million

## Alterations

SNVs, InDels, CNAs, Karyotyping, Fusions, Variant Transcripts, Gene Expression

## 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 <i>in situ</i> Hybridization)
GIST	Her2/Neu, PD-L1 (SP142)	
Glioma	Her2/Neu	MGMT Methylation (Pyrosequencing)
Head & Neck	Her2/Neu, p16, PD-L1 (22c3)	EBER, HPV (Chromogenic <i>in situ</i> 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.



# MI Tumor Seek Hybrid™

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(DNA) SNVs, InDels, CNAs, Karyotyping, Viruses  
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# Easy-to-Interpret Results – Caris Report

## Patient and Specimen Information

<b>Patient</b>	<b>Specimen Information</b>	<b>Ordered By</b>
Name: Date of Birth: Sex: Case Number: TN24 Diagnosis: Ductal carcinoma, NOS	Primary Tumor Site: Breast, NOS Specimen Site: Breast, NOS Specimen ID: Specimen Collected: Test Report Date:	

## Results with Therapy Associations

Contains drug associations ranked by level of evidence:  
**Level 1** = Biomarker test noted in FDA indication  
**Level 2** = Endorsed by clinical guidelines  
**Level 3** = Evidence exists in patient's tumor type

BIOMARKER	METHOD	ANALYTE	RESULT	THERAPY ASSOCIATION	BIOMARKER LEVEL*
AKT1	Seq	DNA-Tumor	Pathogenic Variant Exon 3   p.E17K	<b>BENEFIT</b> capivasertib + fulvestrant	Level 2
				abemaciclib, palbociclib, ribociclib	Level 2
ER	IHC	Protein	Positive   2+, 50%	<b>BENEFIT</b> endocrine therapy	Level 2
				everolimus	Level 2
ER/PR/Her2/Neu	IHC	Protein	HR-Positive HER2-Negative	<b>BENEFIT</b> sacituzumab govitecan	Level 2
PR	IHC	Protein	Positive   2+, 20%	<b>BENEFIT</b> abemaciclib, palbociclib, ribociclib	Level 2
				endocrine therapy	Level 2
ERBB2 (Her2/Neu)	IHC	Protein	HER2-Negative	<b>LACK OF BENEFIT</b> trastuzumab	Level 1
				ado-trastuzumab emtansine (T-DM1)	Level 1
				pertuzumab, margetuximab	Level 2
				lapatinib, neratinib, tucatinib	Level 2

**Biomarker Levels**  
Indicates the strength of evidence and testing (e.g., Level 1 is a FDA CDx).

**Therapies with potential Benefit** are noted in **green**.

**Therapies with potential Lack of Benefit** are noted in **red**.

## Important Note

Contains significant information about drug/biomarker associations and comments from Caris pathologists and/or molecular geneticists, if applicable

**Important Note**  
MI GPSai was performed on this case. Please see Page 5 for results.  
Sacituzumab govitecan is FDA-approved for unresectable locally advanced or metastatic HR-positive, HER2-negative/low breast cancer patients who have received endocrine-based therapy and at least two additional systemic therapies in the metastatic setting.

**Cancer-Type Relevant Biomarkers**  
Pre-defined biomarkers whose results will show regardless of presence or absence of an alteration.

## Therapeutic associations are continuously updated based on:

- FDA approvals
- Industry guidelines
- Literature
- **Physician** feedback

Biomarker	Method	Analyte	Result
AR	IHC	Protein	Positive   1+, 50%
CDH1	Seq	DNA-Tumor	Pathogenic Variant Exon 16   p.Y927fs

*(continued on next page)*  
The selection of any, all, or none of the matched therapies resides solely with the discretion of the treating physician. Decisions on patient care and treatment must be based on the independent medical judgment of the treating physician, taking into consideration all available information concerning the patient's condition, the FDA prescribing information for any therapeutic, and in accordance with the applicable standard of care. Whether or not a particular patient will benefit from a selected therapy is based on many factors and can vary significantly. All trademarks and registered trademarks are the property of their respective owners.

MI Profile sample report for illustrative purposes only. Not for clinical use.

**Clinical Trials**  
Clinical trial information, including Right-In-Time Clinical Trials, can be found later in the report.

# 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.

## Customer Support

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

## Account Implementation Team

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



## Molecular Oncology Specialists

Provides product updates and information, testing capabilities and issue management.

## Precision Medicine Initiatives Team

Assists with technical lab workflows and efficiencies.

## 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](http://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	BTX	EGFR	FAT1	HRAS	MAST2	NFKBIA	POLD3	ROS1	TERT
AR	CALR	EGFRvIII	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	TTFB
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	WTT1
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](http://www.CarisLifeSciences.com).  
 US: 888.979.8669 | [CustomerSupport@CarisLS.com](mailto:CustomerSupport@CarisLS.com)  
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Where Molecular Science Meets Artificial Intelligence.

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