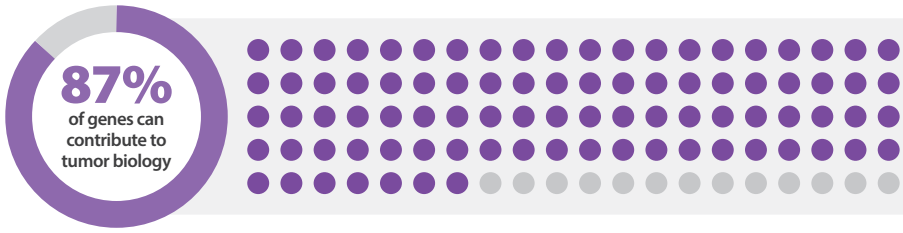
MI Cancer Seek®
Platform

The First and Only Simultaneous WES/ WTS-Based Assay with FDA-approved CDx Indications for Adult and Pediatric Patients to Help Guide Therapy Selection

CARIS®
LIFE SCIENCES

Whole Exome/Whole Transcriptome Sequencing Helps to Identify More Actionable Targets for More Treatment Options

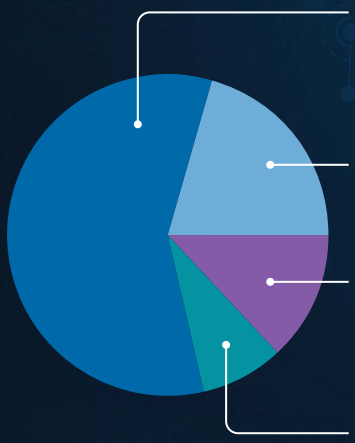
The MI Cancer Seek platform analyzes 23,000+ genes by simultaneous whole exome/whole transcriptome sequencing because almost every gene can play a role in cancer.[1]



Approximately 17,371 human genes have at least one paper published in PubMed. 87% of these genes (15,233 genes) have at least one study that mentions cancer.

By using a WES/WTS-based assay, the MI Cancer Seek platform with professional services provides **the most comprehensive picture for FDA-approved multi-technology therapies.[2]**

The Right Drug Requires the Whole Molecular Picture



DNA Sequencing Drug *(Whole Exome Sequencing for Mutations & CNAs)*

Afatinib	Binimetinib	Cisplatin	Encorafenib	Ivosidenib	Osimertinib	Regorafenib	T-DM1
Alpelisib	Capmatinib	Crizotinib	Erlotinib	Niraparib	Oxaliplatin	Rucaparib	Temozolomide
Amivantamab	Carboplatin	Dabrafenib	Gefitinib	Imatinib	Panitumumab	Sotorasib	Trametinib
Avapritinib	Cetuximab	Cobimetinib	Imatinib	Olaparib	Pembrolizumab	Sunitinib	Vemurafenib

RNA Sequencing Drug *(Whole Transcriptome Sequencing)*

Alectinib	Cabozantinib	Ceritinib	Entrectinib	Larotrectinib	Pemigatinib	Selpercatinib
Brigatinib	Capmatinib	Crizotinib	Erdafitinib	Lorlatinib	Pralsetinib	Tepotinib

IHC Drug *(25+ Biomarkers Available)*

Alectinib	Ceritinib	Enzalutamide	Nivolumab
Atezolizumab	Crizotinib	Everolimus	Ipilimumab
Brigatinib	Endocrine therapy	HER2-targeted therapy	Pembrolizumab
CDK4/6 inhibitors	Entrectinib	Lorlatinib	Sacituzumab govitecan

Other Drug *(CISH, Pyrosequencing)*

HER2-targeted therapy | Sacituzumab govitecan | Temozolomide

- **1 in 4 of the 80+** biomarker-targeted drug therapies are optimally analyzed using RNA sequencing[2]
- **9 in 10** new breast cancer drugs approved by the FDA in 2009-2018 were biomarker-targeted[3]
- **20** biomarker-targeted drugs were approved by the FDA in Q4 of 2025[4]

Note: Copy number alterations ("CNAs").

1. de Magalhães, J.P. Every gene can (and possibly will) be associated with cancer, *Trends in Genetics*, Volume 38, Issue 3, 2022, Pages 216-21
2. https://www.fda.gov/drugs/science-and-research-drugs/table-pharmacogenomic-biomarkers-drug-labeling
3. Leo CP, Leo C, Szucs TD. Breast cancer drug approvals by the US FDA from 1949 to 2018. *Nat Rev Drug Discov.* Jan 2020;19(1):11. doi:10.1038/d41573-019-00201-w.
4. https://www.fda.gov/drugs/resources-information-approved-drugs/oncology-cancerhematologic-malignancies-approval-notifications?TEM=1.

Caris Life Sciences operates several College of American Pathologists (CAP)-accredited, Clinical Laboratory Improvement Amendments (CLIA)-certified, and International Organization for Standardization (ISO)-certified laboratories for sequencing services in Phoenix, Arizona.

MI Cancer Seek Tissue-based Testing to Guide Advanced Cancer Treatment

MI Cancer Seek® is the first and only simultaneous Whole Exome Sequencing (WES) and Whole Transcriptome Sequencing (WTS)-based assay with FDA-approved CDx indications for molecular profiling of solid tumors. MI Cancer Seek is available for adult and pediatric (ages 1-22) patients.

FDA-Approved CDx Indications and Tumor Profiling

MI Cancer Seek is a next-generation sequencing (NGS) based in vitro diagnostic device using total nucleic acid (TNA) isolated from formalin-fixed paraffin embedded (FFPE) tumor tissue specimens for the detection of SNVs, InDels, MSI, TMB in patients with previously diagnosed solid tumors, and CNA in one gene in patients with breast cancer.

MI Cancer Seek is intended as a companion diagnostic to identify patients who may benefit from treatment with the targeted therapies listed in the Companion Diagnostic Indications table, in accordance with the approved therapeutic product labeling.

MI Cancer Seek Companion Diagnostic Indications

Indication	Biomarker	Therapy
Breast Cancer	*PIK3CA* (C420R; E542K; E545A, E545D [1635G>T only], E545G, E545K, Q546E, Q546R; and H1047L, H1047R, H1047Y)	PIQRAY® (alpelisib)
Colorectal Cancer (CRC)	*KRAS* wild-type (absence of mutations in exons 2, 3, and 4) and *NRAS* wild-type (absence of mutations in exons 2, 3, and 4)	VECTIBIX® (panitumumab)
	BRAF V600E	BRAFTOVI® (encorafenib) in combination with ERBITUX® (cetuximab)
Melanoma	*BRAF* V600E	*BRAF* inhibitors approved by FDA*
	BRAF V600E or V600K	MEKINIST® (trametinib) or *BRAF/MEK* inhibitor combinations approved by FDA*
Non-Small Cell Lung Cancer (NSCLC)	*EGFR* exon 19 deletions and exon 21 L858R alterations	*EGFR* Tyrosine Kinase Inhibitors approved by FDA*
Solid Tumors	MSI-H	KEYTRUDA® (pembrolizumab), JEMPERLI® (dostarlimab-gxly)
Endometrial Carcinoma	Not MSI-H	KEYTRUDA® (pembrolizumab) in combination with LENVIMA® (lenvatinib)

Additional Services

Beyond the MI Cancer Seek FDA-approved indications, additional non-CDx sequencing-based features included with testing.

DNA: gLOH, HRD, HLA Genotype, Chromosomal Alterations, Viruses (HHV-8, HPV 16 & 18, EBV, MCPyV)

RNA: Expression, Fusions, Variant Transcripts

AI Signatures: Caris GPSai®, Caris FOLFIRSTai®

MI Cancer Seek Platform: Optional Add-on Testing

Other available tumor type testing can be added to enhance molecular insight.

IHC: 25+ tumor-specific proteins

ISH: HPV, EBER

Pyrosequencing: MGMT Methylation

For Specimen Requirements, Scan QR Code.

*For the most current information about the device indications for the therapeutic products in this group, go to: https://www.fda.gov/medical-devices/in-vitro-diagnostics/list-cleared-or-approved-companion-diagnostic-devices-in-vitro-and-imaging-tools#Group_Labeling

Caris GPSai: Reducing Uncertainty in Cancer of Unknown Primary

Cancer of unknown primary (CUP) is among the ten most common cancer diagnoses worldwide, accounting for 3-5% of all cases.[1] When the tumor's origin is not accurately identified, treatment can be delayed or misdirected, leading to poor patient outcomes.

Without precise molecular insights, care teams often must make decisions without clear direction leaving physician and patients facing the risk of missed treatment opportunities.

Caris GPSai® directly challenges this uncertainty.

In a 2025 validation study[2] across more than 97,000 patients tested, Caris GPSai:

Identified tissue of origin in

84% of CUP cases + **96%** of non-CUP cases

with

95% accuracy

Changed diagnoses in

704 Patients*

Revised diagnoses altered therapy eligibility for **86%** of affected patients

88.7% of physicians indicated that GPSai assisted in making a diagnosis.

By analyzing whole exome (WES) and whole transcriptome sequencing (WTS) data, Caris GPSai uses advanced AI to match a tumor's molecular signature to more than 90 cancer categories. Caris GPSai can be added to MI Cancer Seek® results, providing physicians with a clear pathway and more actionable insights.

Caris GPSai results with MI Cancer Seek, reduces diagnostic uncertainty and provides physicians with the clarity needed to choose the right therapeutic path.

1. Massard, C. et al. (2011) *Nat. Rev. Clin. Oncol.* 8, 701–710
2. Hassan Ghani, et al. GPSai: A Clinically Validated AI Tool for Tissue of Origin Prediction during Routine Tumor Profiling. *Can Res Commun.* 1 September 2025; 5(9): 1477–1489.

*Of 80,000+ patients profiled.

To learn more or order, visit **CarisLifeSciences.com/MICancerSeek**.

CARIS® LIFE SCIENCES

Where Molecular Science Meets Artificial Intelligence.