



# Comprehensive Tumor Profiling

A better guide for  
Molecular Intelligence





# Why Caris?

With the promise of precision medicine becoming a reality, molecular profiling has become standard of care for many cancer types – and required for certain therapies (companion dx). More than ever, oncologists need a trusted tumor profiling partner to provide reliable, high-quality molecular information to guide more precise and individualized treatment decisions.

Caris Molecular Intelligence® identifies key molecular features of cancer and provides clinical insights to aid oncologists in personalizing cancer therapies for their solid tumor cancer patients. Caris Molecular Intelligence helps oncologists:

- **navigate among therapies with potential benefit;**
- **identify therapies that may not have been considered;**
- **determine drugs with potential lack of benefit (avoiding unnecessary toxicities and costs); and**
- **match patients to clinical trials.**

## The Most Experienced Comprehensive Tumor Profiling Provider



### Unmatched Experience

- 2,850,000+ tests completed
- 240,000+ clinical cases performed



### Immunotherapy Diagnostics Expertise

- PD-L1 by IHC, including TPS and CPS scoring methods
- Mismatch Repair (MMR) proteins by IHC: MLH1, MSH2, MSH6, PMS2
- Microsatellite Instability (MSI) by NGS
- Tumor Mutational Burden (TMB) by NGS



### Rigorous Quality Standards

- CAP, CLIA, NYSDOH, ISO15189 accredited
- 66,000-square-foot clinical laboratory in Phoenix, AZ
- 38,000 square-foot R&D facility in Phoenix, AZ
- 115,000-square-foot blood-based laboratory in Irving, Texas (to open in 2021)
- Staffed by: bioinformaticians, oncologists, molecular geneticists, pathologists and PhD scientists



### Limited Tissue Capabilities

- Tumor enrichment via microdissection
- Multiple reflex options to alternative technologies/methods



### Rapid Turnaround Time


- 8-14 calendar days

→ [www.CarisLifeSciences.com](http://www.CarisLifeSciences.com)



# Tumor Profiling

Comprehensive tumor profiling with Caris Molecular Intelligence® assesses DNA, RNA and Proteins with multiple technologies (NGS DNA-WES & RNA-WTS, PyroSeq, IHC, ISH) to reveal a more complete molecular blueprint to guide precise and individualized treatment decisions.




### DNA

Next-Generation Sequencing  
(Mutations, Indels & Copy Number Alterations)

**Whole Exome  
~22,000 genes**

- ✓ 200+ clinically relevant genes
- ✓ 700+ genes sequenced at average 500x and balance of exome at average 200x
- ✓ ~250,000 exonic/ intronic/ intergenic SNPs

All solid tumors




### RNA

Next-Generation Sequencing  
(Fusions & Variant Transcripts)

**Whole Transcriptome  
~22,000 genes**

- ✓ 60 million read counts
- ✓ Gene fusions and variant transcripts
- ✓ Novel translocation detection independent of intronic breakpoint or fusion partner

All solid tumors



### Protein

Immunohistochemistry

**Up to 15  
Clinically Relevant IHCs  
(Optimized across  
~25 Tumor Types)**

- ✓ Multiple FDA approved CDx assays for different disease types (per label)
- ✓ Controls on every IHC slide
- ✓ 4 µm cuts to preserve tissue

All solid tumors

Caris Molecular Intelligence offers two different options for tumor profiling, MI Profile™ and MI Tumor Seek™.

MI PROFILE™

MI TUMOR Seek™

<b>Whole Genome (NGS-DNA)</b>	✓	✓
MSI	✓	✓
TMB	✓	✓
LOH	✓	✓
HRD	Coming Soon	
<b>Whole Transcriptome (NGS-RNA)</b>	✓	✓
<b>IHC, ISH (Protein)</b>	✓	Not Included
<b>TAT</b>	8-14 days	



# Caris MAI™ – Molecular Artificial Intelligence

A revolutionary platform to identify unique “molecular signatures” using artificial intelligence, machine learning and multivariate analysis across the Caris clinical-molecular database to push the boundaries of innovation in precision medicine.



## Genomic Prevalence Score

- Intended for cancer of unknown primary (CUP), or cases with atypical clinical presentation or clinical ambiguity.
- Provides a cancer type similarity assessment by comparing genomic (DNA) and transcriptomic (RNA) characteristics of the patient’s tumor against other tumors in the Caris database.

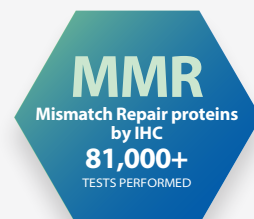
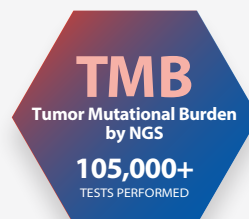
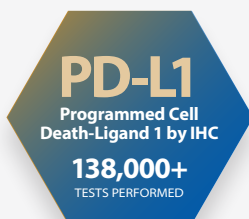


## Frontline Therapy Predictor

- Intended as an aid in gauging a patient’s likelihood to benefit from FOLFOX chemotherapy (in combination with bevacizumab) as the first-line chemotherapy regimen in metastatic colorectal adenocarcinoma.
- Outcomes data from the MI FOLFOXai validation demonstrated a ~50% difference in overall survival.



# Immunotherapy Diagnostics Expertise



By harnessing the body’s immune system to detect and destroy tumor cells, immune checkpoint inhibitors are rapidly ushering in a new era of precision medicine. Identify patients more likely to respond to immunotherapies with reliable molecular information based on validated assays for MMR, MSI, PD-L1 and TMB in our state-of-the-art laboratory.



# MI Trials

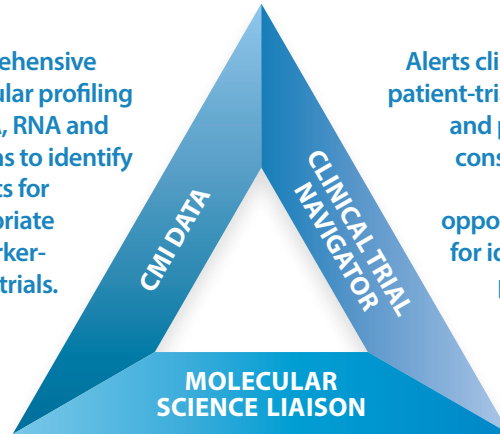
Clinical trials offer patients and physicians access to the latest drugs being developed to improve clinical outcomes. However, awareness of available trials is low and overall participation in oncology trials is less than five percent. Caris helps increase awareness and participation of clinical trials through MI Trials.

## MI Trials provides:

- Real-time alerts to clinicians, matching patients with clinical trials in their area,
- Increased patient access to a larger number of potential treatment options, and
- Unsurpassed clinical trial support through a physician consultant team specializing in oncology.

**Comprehensive molecular profiling of DNA, RNA and proteins to identify patients for appropriate biomarker-driven trials.**

**Alerts clinician of patient-trial match and provides consultation on trial opportunities for identified patients.**



**Provides physician with expertise on CMI results.**



# MI Report

Caris Molecular Intelligence reports are built to maximize clinical utility in an easy-to-interpret format. Clinicians need treatment information fast, that's why our report was built by oncologists for oncologists. With results back in 8-14 days, we'll help you find answers when you need them the most.

Contains important biomarker and associated therapy results

Provides important information about drug/ biomarker associations and comments from Caris pathologists and/or molecular geneticists

Lists disease-relevant biomarker information, as well as other altered biomarker results

Navigate among therapies with potential benefit (noted in green)

Identify therapies with potential lack of benefit (noted in red)

**MI PROFILE** Final Report | **CARIS** LIFE SCIENCES

**Patient**  
 Name: Patient, Test  
 Date of Birth: XX/Mon/19XX  
 Sex: Male  
 Case Number: TN19-XXXXXX  
 Diagnosis: Mucinous adenocarcinoma

**Specimen Information**  
 Primary Tumor Site: Transverse colon  
 Specimen Site: Liver  
 Specimen ID: ABC-1234-XYZ  
 Specimen Collected: XX-Mon-2019  
 Completion of Testing: XX-Mon-2019

**Ordered By**  
 Ordering Physician, MD  
 Cancer Center  
 123 Main Street  
 Springfield, XY 12345, USA  
 1 (123) 456-7890

BIOMARKER	METHOD	RESULT	THERAPY ASSOCIATION	BIOMARKER LEVEL*
Mismatch Repair Status	IHC	Deficient	<b>BENEFIT</b> nivolumab, nivolumab/ipilimumab combination, pembrolizumab	Level 1
MSI	NGS	High	<b>BENEFIT</b> Irinotecan + [cetuximab or panitumumab] + vemurafenib	Level 2
BRAF	NGS	Mutated, Pathogenic Exon 15 [p.V600E]	<b>LACK OF BENEFIT</b> vemurafenib/dabrafenib monotherapy	Level 3A
ERBB2 (Her2/Neu)	CISH	Amplified	<b>BENEFIT</b> lapatinib, pertuzumab, trastuzumab	Level 3A

\* Biomarker reporting classification: Level 1 - highest level of clinical evidence and/or biomarker association included on the drug label; Level 2 - strong evidence of clinical significance and is endorsed by standard clinical guidelines; Level 3 - potential clinical significance (3A - evidence exists in patient's tumor type, 3B - evidence exists in another tumor type).

**Important Note**  
 This patient has a potential NCI-MATCH Trial-eligible result. Please see Clinical Trial see page 6

**Additional Results**


CANCER TYPE RELEVANT BIOMARKERS			CANCER TYPE RELEVANT BIOMARKERS	
Biomarker	Method	Result	Biomarker	Result
NTRK1	RNA-Seq	Fusion Not Detected	PTEN	IHC
NTRK2	RNA-Seq	Fusion Not Detected	OTHER FINDINGS	
NTRK3	RNA-Seq	Fusion Not Detected	Biomarker	
Tumor Mutational Burden				
ERBB2 (Her2/Neu)				


**MI PORTAL**

Utilize the Clinical Trials Connector to match biomarkers with open clinical trials through MI Portal




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