Molecular Profiling Requisition

Phone: (888) 979-8669 | Fax: (866) 479-4925 | Email: CustomerSupport@CarisLS.com

Please complete and return by fax or email. Incomplete or missing data may result in delayed testing.

CARIS LIFE SCIENCES

TREATING ONCOLOGIST INFORMATION

Name		NPI
Physician Email	Office Contact Name	
Office/Hospital Name	Address	
City	State	Zip
Phone	Fax	

PATIENT INFORMATION

Last Name	First Name		MI
In-Office Medical Record Number	DOB	Biological Sex ☐M ☐F	Ethnicity
Address			Apt.
City		State	Zip
Mobile Phone	Email		

PATHOLOGY INFORMATION

Pathology Services/Specimen Storage Location		
Address/Suite		
City		State
Phone	Fax	Zip

SURGEON/PA/APRN or PERSON COMPLETING REQUISITION

Name	Facility	
Address	City	State
Phone	Fax	Zip
Role ☐Surgeon ☐PA ☐MA ☐APRN ☐Other:_____		

BILLING INFORMATION *(Attach the front and back of PRIMARY and SECONDARY insurance cards. Patient insurance/payment is REQUIRED to begin testing.)*

☐ Insurance ☐ Self Pay
☐ Medicare ☐ Direct Bill (contracted)
☐ HMO, Referral #: _____
☐ Other: _____

	Insurance Provider	Policy #	Group #	Insured Name	Insured DOB	Relationship to Patient	Prior Authorization #
Primary							
Secondary							

CLINICAL/SPECIMEN INFORMATION *(Include a copy of the pathology report and medical records that support the need for testing.)*

ICD-10 Code(s) (Provide as many symptomatic diagnosis codes as applicable)	Primary Tumor Site	Clinical Stage ☐I ☐II ☐III ☐IV	Most Recent Tissue Specimen ☐Yes ☐No

TISSUE-BASED TESTING

Specimen Collection Location (Place of Service)	Specimen Type(s) ☐Formalin Fixative ☐FFPE Block ☐Unstained Slides
☐Hospital Inpatient: Discharge Date _____	Specimen ID#(s)
☐Hospital Inpatient, Not Yet Discharged	Specimen Site (anatomical location)
☐Hospital Outpatient: Discharge Date _____	Collection Date & Time (MM/DD/YYYY)
☐Office/ASC	
☐Other: _____	
Facility Name Where Procedure Performed/Collected	Date Removed from Storage (MM/DD/YYYY)

BLOOD-BASED TESTING

Specimen Collection Location (Place of Service)	Specimen Type(s) ☐Whole Blood
☐Hospital Inpatient: Discharge Date _____	Specimen Site ☐Venous ☐Port
☐Hospital Inpatient, Not Yet Discharged	Collection Date & Time (MM/DD/YYYY)
☐Hospital Outpatient: Discharge Date _____	
☐Office/ASC	
☐Other: _____	
Facility Name Where Procedure Performed/Collected	Date Removed from Storage (MM/DD/YYYY)

MOLECULAR PROFILING TESTING OPTIONS *(See reverse side for test descriptions and specimen requirements.)*

TISSUE-BASED TESTING

MI Profile™ Comprehensive Testing

☐ **MI Tumor Seek Hybrid™ + IHCs and Other Tests by Tumor Type**
☐ Include Caris GPSai™ reporting for cancer type similarity assessment.

Next-Generation Sequencing Only

☐ **MI Tumor Seek Hybrid™**
☐ Include Caris GPSai™ reporting for cancer type similarity assessment.

BLOOD-BASED TESTING

Next-Generation Sequencing

☐ **Caris Assure™**
Does the patient have a history of hematologic malignancy, MDS, bone marrow/stem cell/solid organ transplant?
☐ Yes, please specify: _____
☐ No
☐ Mobile phlebotomy requested.

PLACE PATIENT ID/SPECIMEN LABEL HERE (Blood Only)

Concurrent Testing: If ordering both tissue- and blood-based testing, I will provide medical records documenting the need for concurrent testing and I certify that:

☐ Ordering both tissue- and blood-based profiling concurrently is medically necessary and will assist me in treating my patient.
☐ Oncology guidelines support concurrent testing in this disease state.
☐ Turnaround time for tissue-based testing may delay important treatment decisions.
☐ The available tissue may not meet testing requirements.
☐ Other:

MEDICAL NECESSITY / SPECIAL INSTRUCTIONS / ADDITIONAL CC PHYSICIAN CONTACT INFORMATION

ATTESTATION & PATIENT CONSENT

This requisition constitutes an order for molecular testing from Caris MPI, Inc. (Caris) I certify (a) the services are medically necessary and will assist me in treating my patient, (b) the patient has sufficient performance status to receive additional treatment, (c) I will make available patient medical records documenting the foregoing, and (d) I supplied information to the patient regarding this testing, explained the purpose of this testing to the patient, and obtained informed consent for (i) such testing, (ii) any analysis and reports related to such testing, (iii) Caris to retain testing results, samples and related information and analysis, (iv) Caris' use or disclosure (including to third parties) of deidentified information generated from such testing for general research and other purposes, (v) Caris' disclosure of testing results and information to third-party payers in connection with such testing, and (vi) for Caris to contact the patient regarding the testing.

Authorized Provider Signature:

Provider Name (Print):

Date:

Test Descriptions

The biomarkers included in the options below may change from time-to-time. Before ordering, please refer to the website, www.CarisLifeSciences.com/profiling-menu, to view intended use and the definitive list of available biomarkers and the specific biomarkers analyzed by tumor type.

TISSUE	**MI Profile™** *Comprehensive Testing*	MI Tumor Seek Hybrid™ + IHCs and Other Tests by Tumor Type. Tissue-based Whole Exome Sequencing 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.
	MI Tumor Seek Hybrid™ *Next-Generation Sequencing*	Tissue-based Whole Exome Sequencing and Whole Transcriptome Sequencing analysis. Caris FOLFIRSTai™ is performed for mCRC cases and Caris GPSai™ is performed for CUP cases.
	Caris GPSai™	Cancer type similarity assessment that is intended to help identify the tumor of origin by comparing the molecular characteristics of the patient's tumor against other tumors in the Caris database.
	Caris FOLFIRSTai™	Chemotherapy response predictor that is 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	**Caris Assure™**	Blood-based Whole Exome and Whole Transcriptome Sequencing for pathogenic and likely pathogenic tumor-derived, incidental germline, and incidental CHIP variant detection. Caris Assure™ is intended for patients with previously diagnosed solid malignant neoplasms where tissue is not available, and is to be used by qualified healthcare professionals. RNA results are intended for investigational purposes only. Not a replacement for comprehensive germline testing. Incidental pathogenic alterations detected in ACMG recognized cancer genes are reported. Negative results do not imply the patient does not harbor a germline mutation.

Checklist for Ordering

- ☐ Requisition (Completed, Signed and Dated)
- ☐ Insurance Information (Insurance Card Preferred); including Referral Number for HMO Plans
- ☐ Patient Consent (Completed, Signed and Dated)
- ☐ Pathology Report(s)
- ☐ Patient Progress Note(s) /Medical Record(s)
- ☐ Sufficient Tumor Specimen

Note: Customer Support may contact your office to obtain certain medical records that may be required by patient's insurance company (e.g. 90-day clinical history, physical exam, and additional notes, including: daily progress, treatment, doctors and office).

Formalin Fixed Paraffin Embedded (FFPE) Samples

Sufficient tumor (≥ 20% tumor nuclei) must be present to complete all analysis. If you have any questions, please contact Customer Support at (888) 979-8669.

SPECIMEN TYPE	SPECIMEN REQUIREMENTS
Fixed Tissue	One (1) tumor-containing formalin fixed paraffin embedded block (FFPE) from most recent surgery or biopsy. Successive four (4) micron sections will be created from the block until sufficient material for the testing orders is obtained. For the molecular analysis, tumor cells will be excised by microdissection.
Unstained Slides	Unstained, positively charged, unbaked slides from one single, tumor-containing formalin fixed paraffin embedded block; 4 micron sections. • **Tumor content: ≥20% tumor nuclei** • **MI Tumor Seek Hybrid™:** 10 slides; 25 slides if ordering additional tumor-specific testing (IHC, ISH, etc.) Note: Specimens with a smaller tumor area may require additional specimen to be submitted.
Core Needle Biopsy	Four to six (4-6) biopsies with 18 gauge needle preferred. Six to ten (6-10) biopsies with 22 gauge needle accepted. (Preparation in 10% neutral buffered formalin.)
Fine Needle Aspirate (FNA)	One (1) formalin fixed paraffin embedded block containing sufficient tumor. **Please do NOT use non-formalin-based fixatives, including alcohol-based fixatives.**
Malignant Fluid Cell Block	One (1) formalin fixed paraffin embedded cell block containing sufficient tumor (20% or more tumor nuclei). **Please do NOT use non-formalin-based fixatives, including alcohol-based fixatives.**
Bone/Bone Metastasis	One (1) formalin fixed paraffin embedded block of tumor (primary bone malignancy or metastasis to the bone) decalcified using EDTA based method(s) or non-decalcified specimen.

Fresh Samples

All fresh samples should be shipped overnight to be received within 48 hours. Sufficient tumor must be present to complete all analysis. If you have any questions, please contact Customer Support at (888) 979-8669.

SPECIMEN TYPE	SPECIMEN REQUIREMENTS
Fresh Tissue	Two (2) or more samples with a maximum thickness of 3-4mm (height, width, length) and submit in 10% neutral buffered formalin.
Core Needle Biopsy	Four to six (4-6) biopsies with 18 gauge needle preferred. Six to ten (6-10) biopsies with 22 gauge needle accepted. Place in 10% neutral buffered formalin.
Bone/Bone Metastasis	Two (2) or more samples with maximum thickness of 3-4mm (height, width, length) and submit in 10% neutral buffered formalin **(DO NOT DECALCIFY).**
Whole Blood	**Two (2) 10 mL PAXgene® Blood ccfDNA tubes of whole blood. Invert 10x. Do not shake. Do not freeze. Ship room temperature.**

Insufficient Specimen Quantity – Prioritization of Tests

In the event that a specimen is received with an insufficient quantity of tissue or insufficient percent of tumor required to perform the entire profile or individual tests indicated on the requisition, the Caris pathologist will prioritize and order the appropriate testing unless otherwise indicated by the ordering physician. If limited tissue communication is requested before moving forward with testing, Caris will fax the ordering physician the proposed list of tests. The physician may amend the suggested list to include any tests that are offered within the test menu. The ordering physician should review the proposed list of tests within 48 hours in order to provide timely results. Please note: turnaround time may be longer for specimens with limited tissue.

In certain circumstances, CMS requires that Caris bill the hospital for testing. For more information, please call (888) 979-8669.

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