

Tumor Profiling Requisition



Phone: (888) 979-8669 | Fax: (866) 479-4925 | Email: CustomerSupport@CarisLS.com Please complete and return by fax or email.

Customer Support may contact your office to obtain certain medical records that may be required by patient's insurance provider.

TREATING ONCOLOGIST INFORMATION			PATIENT INFORMATION			
Name	NPI		Last Name	First Name	MI	
Physician Email	Office Contact Name		In-Office Medical Record Number	DOB	Gender <input type="checkbox"/> M <input type="checkbox"/> F	Ethnicity
Office/Hospital Name	Address		Address			Apt.
City	State	Zip	City		State	Zip
Phone	Fax		Phone		Work Phone or Email	

PATHOLOGY INFORMATION			SURGEON/PA/APRN or PERSON COMPLETING REQUISITION			
Pathologist/Pathology Services			Name		Facility	
Hospital			Address		City	State
City		State	Phone		Fax	Zip
Phone	Fax	Zip	Role <input type="checkbox"/> Surgeon <input type="checkbox"/> PA <input type="checkbox"/> MA <input type="checkbox"/> APRN <input type="checkbox"/> Other: _____			

BILLING INFORMATION (Attach the front and back of PRIMARY and SECONDARY insurance cards. Patient insurance/payment is REQUIRED to begin testing.)							
<input type="checkbox"/> Insurance <input type="checkbox"/> Self Pay <input type="checkbox"/> Medicare <input type="checkbox"/> Direct Bill (contracted) <input type="checkbox"/> HMO, Referral #: _____ <input type="checkbox"/> 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)		Clinical Stage	Current Line of Therapy		
Specimen Collection Location (Place of Service Code): <input type="checkbox"/> Office/Clinic (11) <input type="checkbox"/> Hospital Inpatient (21) – Date of Discharge: _____ <input type="checkbox"/> Hospital Outpatient/ASC (22) <input type="checkbox"/> Non-Hospital ASC (24) <input type="checkbox"/> Skilled Nursing Facility (32) <input type="checkbox"/> Hospice (34)					
Specimen Collection Facility (Place of Service)		Primary Tumor Site	Specimen Site	Specimen/Block ID#(s)	
Specimen Type(s): <input type="checkbox"/> FFPE Block <input type="checkbox"/> Unstained Slides <input type="checkbox"/> Formalin Fixative		Collection Date & Time <input type="checkbox"/> AM <input type="checkbox"/> PM / /	Most Recent Specimen <input type="checkbox"/> Yes <input type="checkbox"/> No	Date Removed From Storage (Medicare Only) / /	Duration of Fixation (FFPE Blocks)

CARIS MOLECULAR INTELLIGENCE®

To order, please select from the options below. **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 the definitive list of available biomarkers and the specific biomarkers analyzed by tumor type.**

TUMOR PROFILING OPTIONS (Choice required). If the specimen is insufficient to perform the ordered tests, limited tissue testing recommendations by Caris pathologists will be performed unless otherwise indicated in the special instructions section or by providing specific instructions in advance to Caris Customer Support.

- MI Profile™ – Multi-platform, solid tumor biomarker analysis.** The technology platforms used and biomarkers tested may vary based on the tumor type submitted. Technologies include: NGS (whole exome sequencing for DNA mutations, copy number alterations, insertions/deletions, genomic signatures: LOH, MSI, TMB; and whole transcriptome sequencing for RNA fusions and variant transcripts), pyro sequencing, IHC, *in situ* hybridization. MI FOLFOXai™ will be performed for metastatic colorectal adenocarcinoma cancer cases.
- MI Tumor Seek™ – NGS analysis.** Whole exome sequencing for DNA mutations, copy number alterations, insertions/deletions, genomic signatures LOH, MSI, and TMB, and whole transcriptome sequencing for RNA fusions and variant transcripts. MI FOLFOXai™ will be performed for metastatic colorectal adenocarcinoma cancer cases.
Add Immuno-Oncology IHC biomarkers (included in MI Profile):
 PD-L1 MMR (MLH1, MSH2, MSH6, PMS2)

- MI GPsai™:** Cancer type similarity assessment consisting of algorithmic analyses of the genomic (DNA) and transcriptomic (RNA) characteristics of the tumor as compared to more than 20 distinct tumor types in the Caris database. *Only available if MI Profile or MI Tumor Seek is ordered.*

ADDITIONAL TESTING (Choice required)

Ambray Genetics® Germline Genetic Testing: Please complete the Ambray Genetics-Caris Life Sciences Germline Genetic Testing Requisition Form to submit an order.

- CancerNext-Expanded® NGS analysis of 77 genes from whole blood for hereditary cancer detection (DNA only)
- CancerNext-Expanded®+RNAinsight® additional 18 genes for RNA analysis (DNA and RNA)

SPECIAL INSTRUCTIONS/ADDITIONAL PHYSICIAN INFO (name, email, fax):

Attestation: This requisition constitutes an order for molecular testing from Caris MPL, Inc. 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 maintain and will make available patient medical records documenting the foregoing, (d) I have supplied information to the patient regarding this testing, and (e) if order is placed by pathologist, I certify this order for services is supported by my institution's medical policy and/or was deemed medically necessary by the patient's treating physician.	Physician/Authorized Provider Signature	Print Name	Date
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PLEASE SEE THE REVERSE FOR CMS BILLING, PATIENT CONSENT REQUIREMENTS AND OPTIMAL SPECIMEN REQUIREMENTS.

Patient Consent

Physician will be solely responsible for confirming that legally effective informed consent has been obtained from the patient or his/her authorized representative as required by applicable state law. By ordering a test from Caris Life Sciences®, physician certifies that this consent is in place and that test results will be used and disclosed only in accordance with applicable law.

Checklist for Ordering Caris Molecular Intelligence

- | | |
|--|--|
| <input type="checkbox"/> Requisition (Completed, Signed and Dated) | <input type="checkbox"/> Pathology Report(s) |
| <input type="checkbox"/> Insurance Information (Insurance Card Preferred); including Referral Number for HMO Plans | <input type="checkbox"/> Patient Progress Note(s) /Medical Record(s) |
| | <input type="checkbox"/> 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 until a total area of at least 25 mm ² (5mm x 5mm) is obtained.
Unstained Slides	Unstained, positively charged, unbaked slides from one single, tumor-containing formalin fixed paraffin embedded block; 4 micron sections. <ul style="list-style-type: none"> • 5mm x 5mm x 4µm tissue/slide • MI Profile™: 25 slides • MI Tumor Seek™: 10 slides Note: Specimens with a smaller tumor area may require additional specimen to be submitted. If the tumor area per slide exceeds 25mm ² , fewer slides are needed for testing.
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 (Ambry Genetics Germline Genetic Testing Only)	Use ONLY the blood collection tubes supplied in the Caris Blood Shipper Kit: Two (2) 10 mL PAXgene® Blood ccfDNA tubes of whole blood. If RNA analysis desired, also use the one (1) PAXgene Blood RNA tube to collect additional sample using instructions in kit. For all tubes: 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 Life Sciences 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 Life Sciences bill the hospital for the technical component and the clinical laboratory services component. For more information, please call (888) 979-8669.