

Molecular Profiling Test Request Form

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

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

For Project ID Use Only



TREATING PHYSICIAN INFORMATION <i>Section required.</i>			PATIENT INFORMATION <i>Section required.</i>			
Name	NPI		Last Name	First Name	MI	
Physician Email	Office Contact Name		In-Office Medical Record Number	DOB	Biological Sex <input type="checkbox"/> M <input type="checkbox"/> F	Ethnicity
Office/Hospital Name	Address		Address			Apt.
City	State	Zip	City		State	Zip
Phone	Fax		Mobile Phone		Email	

MOLECULAR PROFILING TESTING OPTIONS <i>Selection required. For specimen collection instructions, please see technical specification on the Caris website.</i>	
TISSUE -BASED TESTING	BLOOD-BASED TESTING
<input type="checkbox"/> MI Cancer Seek® (CDx) + IHCs and Additional Molecular Tests by Tumor Type <input type="checkbox"/> Include Caris GPSai™ reporting for cancer type similarity assessment <input type="checkbox"/> MI Cancer Seek® (CDx) <input type="checkbox"/> Add MGMT by pyrosequencing for glioma cases <input type="checkbox"/> Include Caris GPSai™ reporting for cancer type similarity assessment <input type="checkbox"/> Add IHC Testing <input type="checkbox"/> CLDN18 <input type="checkbox"/> FOLR1 <input type="checkbox"/> Her2 <input type="checkbox"/> MET <input type="checkbox"/> MMR <input type="checkbox"/> PD-L1 <input type="checkbox"/> Other _____ <i>If sample does not meet specimen requirements, the order will reflex to MI Tumor Seek Hybrid™ (LDT).</i> Select box below to reflex to Caris Assure If ordering tissue only and tissue submitted does not meet criteria for successful testing. <input type="checkbox"/> Reflex to Caris Assure® <input type="checkbox"/> Exclude incidental germline results <input type="checkbox"/> Exclude DPYD results <input type="checkbox"/> Caris phlebotomy services requested <input type="checkbox"/> Does the patient have a history of: <input type="checkbox"/> Hematologic malignancy <input type="checkbox"/> MDS <input type="checkbox"/> Bone marrow/stem cell/solid organ transplant <input type="checkbox"/> None	<input type="checkbox"/> Caris Assure® <input type="checkbox"/> Exclude incidental germline results <input type="checkbox"/> Exclude DPYD results <input type="checkbox"/> Caris phlebotomy services requested <input type="checkbox"/> Does the patient have a history of: <input type="checkbox"/> Hematologic malignancy <input type="checkbox"/> MDS <input type="checkbox"/> Bone marrow/stem cell/solid organ transplant <input type="checkbox"/> None Is tissue specimen from a recent procedure available? <input type="checkbox"/> Yes <input type="checkbox"/> No Tissue testing resulted in Quantity Not Sufficient <input type="checkbox"/> Yes <input type="checkbox"/> No PLACE PATIENT ID/SPECIMEN LABEL HERE (Blood Only)

SPECIAL INSTRUCTIONS/ADDITIONAL CC PHYSICIAN CONTACT INFORMATION (OPTIONAL)		
Special Instructions		
Additional Physician Name to be Copied	Facility Name	Additional Physician Email

PATHOLOGY INFORMATION <i>Section required, if submitting tissue specimen.</i>			
Pathology Services/Specimen Storage Location	Address/Suite	City	
State	Zip	Phone	Fax

BILLING INFORMATION <i>Attach the front and back of PRIMARY and SECONDARY insurance cards. Patient insurance/payment is REQUIRED to begin testing.</i>							
<input type="checkbox"/> Insurance <input type="checkbox"/> Self Pay	Insurance Provider	Policy #	Group #	Insured Name	Insured DOB	Relationship to Patient	Prior Authorization #
<input type="checkbox"/> Direct/Client Bill # _____	Primary						
<input type="checkbox"/> HMO/Referral # _____	Secondary						
<input type="checkbox"/> Other _____							

CLINICAL/SPECIMEN INFORMATION <i>Selection required. Include a copy of the pathology report and medical records that support the need for testing.</i>				
Primary ICD-10	Clinical Stage <input type="checkbox"/> II <input type="checkbox"/> III <input type="checkbox"/> IV	Date of Original Diagnosis (MM/DD/YYYY)	Disease Status at Time of Testing (select all that apply) <input type="checkbox"/> Metastatic <input type="checkbox"/> Refractory <input type="checkbox"/> Recurrent <input type="checkbox"/> Unresectable <input type="checkbox"/> Relapsed <input type="checkbox"/> None of these	Patient is Seeking Further Treatment and is <input type="checkbox"/> Newly Diagnosed <input type="checkbox"/> Not Responding to Therapy
Primary Tumor Site		Facility Where Procedure Performed/Collected		
Tissue Specimen Collection Date & Time (MM/DD/YYYY)	<input type="checkbox"/> Hospital Inpatient <input type="checkbox"/> Hospital Outpatient <input type="checkbox"/> Office/Non-Hospital	<input type="checkbox"/> Not yet discharged OR <input type="checkbox"/> Discharge date: _____	Specimen Type(s) <input type="checkbox"/> FFPE Block <input type="checkbox"/> Unstained Slides <input type="checkbox"/> Formalin Fixative <input type="checkbox"/> Whole Blood	Blood Sample Draw <input type="checkbox"/> Venous <input type="checkbox"/> Port
Date Tissue Sample Removed from Storage (MM/DD/YYYY)	Tissue Specimen ID#(s)		Specimen Site (anatomical location)	Blood Specimen Collection Date & Time (MM/DD/YYYY)

ADDITIONAL INFORMATION ON NEXT PAGE

MI CANCER SEEK® FDA COMPANION DIAGNOSTIC INDICATIONS *Selection required.*

INDICATIONS		BIOMARKERS	FDA-APPROVED THERAPY
<input type="checkbox"/>	Breast Cancer	PIK3CA (C420R, E542K, E545A, E545D [1635G>T only], E545G, E545K, Q546E, Q546R; and H1047L, H1047R, H1047Y)	PIQRAY® (alpelisib)
<input type="checkbox"/>	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)
<input type="checkbox"/>		BRAF V600E	BRAFTOVI® (encorafenib) in combination with ERBITUX® (cetuximab)
<input type="checkbox"/>	Melanoma	BRAF V600E	BRAF inhibitors approved by FDA*
<input type="checkbox"/>		BRAF V600E or V600K	MEKINIST® (trametinib) or BRAF/MEK inhibitor combinations approved by FDA*
<input type="checkbox"/>	Non-Small Cell Lung Cancer (NSCLC)	EGFR exon 19 deletions and exon 21 L858R alterations	EGFR Tyrosine Kinase Inhibitors approved by FDA*
<input type="checkbox"/>	Solid Tumors	MSI-H	KEYTRUDA® (pembrolizumab), JEMPERLI® (dostarlimab-gxly)
<input type="checkbox"/>	Endometrial Carcinoma	Not MSI-H	KEYTRUDA® (pembrolizumab) in combination with LENVIMA® (lenvatinib)
<input type="checkbox"/>	If other indications for testing apply, please check here.		

*For the most current information about the device indications for the therapeutic products in this group, visit the FDA website for "[Device Indication for a Specific Group of Oncology Therapeutic Products](#)."

PIQRAY® is a registered trademark of Novartis AG. VECTIBIX® is a registered trademark of Immunex Corporation. BRAFTOVI® is a registered trademark of Array BioPharma Inc. in the United States and various other countries. ERBITUX® is a registered trademark of ImClone LLC, a wholly owned subsidiary of Eli Lilly and Company. MEKINIST® is a registered trademark of Novartis AG Corporation Switzerland. KEYTRUDA® is a registered trademark of Merck. JEMPERLI® (dostarlimab-gxly) is a registered trademark owned by the GSK group of companies. LENVIMA® (lenvatinib) is a registered trademark used by Eisai Inc. under license from Eisai R&D Management Co., Ltd.

PHYSICIAN ATTESTATION OF MEDICAL NECESSITY *Signature required.*

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.

I further attest that if this order is for concurrent tissue and blood profiling, or if both are ordered within the same 30-day period, that both tests will assist me in treating my patient and is medically necessary based on several clinical factors, which may include, oncology guidelines support concurrent testing in this disease state, turnaround time for tissue-based testing may delay important treatment decisions, or the available tissue may not meet testing requirements, among others. Additionally, I will provide any requested medical records necessary to support concurrent testing.

Authorized Provider Signature *I have conferred with the treating provider and am ordering per his/her request for use in determining treatment options for their patient.*

Provider Name (Print)

Date

TEST DESCRIPTIONS

	TISSUE	BLOOD
	MI Cancer Seek® (CDx) <i>Next-Generation Sequencing</i>	MI Cancer Seek® is a NGS-based <i>in vitro</i> diagnostic device that uses total nucleic acid isolated from formalin-fixed paraffin-embedded tumor tissue specimens and a broad, multi-gene panel to detect several types of genomic alterations via a combined WES/WTS platform. MI Cancer Seek is intended as a companion diagnostic (CDx) 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 is available for adult and pediatric (ages 1-22) patients. Additionally, MI Cancer Seek is intended to provide tumor mutational profiling to be used by qualified healthcare professionals in accordance with professional oncology guidelines for cancer patients with solid malignant neoplasms. Genomic findings other than those listed in the Companion Diagnostic Indications table are not prescriptive or conclusive for labeled use of any specific therapeutic product. See website for complete product information, including companion diagnostic indications and performance characteristics.
	MI Tumor Seek Hybrid™ (LDT) <i>Next-Generation Sequencing</i>	MI Tumor Seek Hybrid™ is a NGS-based laboratory-developed test that uses WES/WTS to analyze DNA and RNA extracted from tumor tissue to detect multiple types of genomic alterations. Caris FOLFIRSTai® is performed for mCRC cases and Caris GPSai™ is performed for CUP cases. MGMT by pyrosequencing for glioma cases can be added to results.
	Caris GPSai™	Caris GPSai™ is a cancer type similarity assessment intended to help identify tumor of origin by matching a tumor's molecular signature to the Caris genomic and transcriptomic database.
	Caris FOLFIRSTai®	Caris FOLFIRSTai® is a 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.
	Caris Assure®	Blood-based Whole Exome and Whole Transcriptome Sequencing for pathogenic and likely pathogenic tumor-derived, incidental germline, and incidental CH variant detection. Caris Assure® is intended for patients with previously diagnosed solid malignant neoplasms where tissue is not feasible 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 are reported, including ACMG recognized cancer genes. Negative results do not imply the patient does not harbor a germline mutation. Not intended for patients with a history of bone marrow, stem cell, or solid organ transplant.