MI Cancer Seek® Tissue Molecular Profiling Test Request Form for New York State

For Project ID Use Only

CARIS LIFE SCIENCES

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

TREATING PHYSICIAN INFORMATION

Section required.

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

PATIENT INFORMATION

Section required.

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

MOLECULAR PROFILING TESTING OPTIONS

Selection required. For specimen collection instructions, please see technical specification on the Caris website.

☐ **MI Cancer Seek® (CDx) + IHCs and Additional Molecular Tests by Tumor Type**

☐ *Include* Caris GPSai™ reporting for cancer type similarity assessment

If sample does not meet specimen requirements, the order will reflex to MI Tumor Seek Hybrid™ (LDT).

☐ **MI Cancer Seek® (CDx)**

☐ *Add* MGMT by pyrosequencing for glioma cases

☐ *Include* Caris GPSai™ reporting for cancer type similarity assessment

☐ *Add* IHC Testing

☐ CLDN18 ☐ FOLR1 ☐ Her2 ☐ MET ☐ MMR ☐ PD-L1

☐ Other _____

SPECIAL INSTRUCTIONS/ADDITIONAL CC PHYSICIAN CONTACT INFORMATION (OPTIONAL)

Special Instructions		
Additional Physician Name to be Copied	Facility Name	Additional Physician Email

PATHOLOGY INFORMATION

Section required, if submitting tissue specimen.

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

BILLING INFORMATION

Attach the front and back of PRIMARY and SECONDARY insurance cards. Patient insurance/payment is REQUIRED to begin testing.

☐ Insurance ☐ Self Pay

☐ Direct/Client Bill # _____

☐ HMO/Referral # _____

☐ Other _____

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

CLINICAL/SPECIMEN INFORMATION

Selection required. Include a copy of the pathology report and medical records that support the need for testing.

Primary ICD-10 Primary Tumor Site	Clinical Stage ☐ II ☐ III ☐ IV	Date of Original Diagnosis (MM/DD/YYYY)	Disease Status at Time of Testing (select all that apply) ☐ Metastatic ☐ Refractory ☐ Recurrent ☐ Unresectable ☐ Relapsed ☐ None of these	Patient is Seeking Further Treatment and is: ☐ Newly Diagnosed ☐ Not Responding to Therapy

Specimen Collection Date & Time (MM/DD/YYYY)	☐ Hospital Inpatient ☐ Not yet discharged *OR* ☐ Hospital Outpatient ☐ Discharge date: _____ ☐ Office/Non-Hospital	Specimen Type(s) ☐ FFPE Block ☐ Unstained Slides ☐ Formalin Fixative

Facility Where Procedure Performed/Collected	Tissue Specimen ID#(s)	Specimen Site (anatomical location)	Date Tissue Sample Removed from Storage (MM/DD/YYYY)

ADDITIONAL INFORMATION ON NEXT PAGE

MI CANCER SEEK® FDA COMPANION DIAGNOSTIC INDICATIONS

Selection required.

	INDICATIONS	BIOMARKERS	FDA-APPROVED 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)
☐	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.

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	**MI Cancer Seek® (CDx)** *Next-Generation Sequencing*	MI Cancer Seek® is a NGS-based *in vitro* 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) *Next-Generation Sequencing*	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.