Molecular Profiling Requisition – International

Phone: 00 41 21 533 53 00 | Fax: 00 41 21 533 53 01 | Email: InternationalSupport@CarisLS.com.
Please complete and return by fax or email. Incomplete or missing data may result in delayed testing.

TREATING ONCOLOGIST INFORMATION

Name	Caris Account Number/ Distributor	
Physician Email	Office Contact Name	
Office/Hospital Name	Address	
City	Country	Postal Code
Phone	Fax	

PATIENT INFORMATION

Last Name	First Name		MI
In-Office Medical Record Number	DOB (DD/MM/YYYY)	Biological Sex ☐M ☐F	Ethnicity
Address			Apt.
City	Country		Postal Code
Mobile Phone	Email		

PATHOLOGY INFORMATION

Pathology Services/Specimen Storage Location	Address/Suite	
City	Country	Postal Code
Phone	Fax	

BILLING INFORMATION

☐ **Self-pay:** Payment is required before testing starts. Caris Customer Support will contact the patient directly to agree payment terms.

☐ **Health Insurance:** A reimbursement request has been sent to patient's health insurance.

Insurance Company: _____ Policy #: _____ Pre-Authorisation / Authorisation #: _____ *(if available)*

☐ **Hospitals/Clinics:** Institution will be billed after testing has been performed.

☐ **Other**, please specify: _____

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 ☐ I ☐ II ☐ III ☐ IV
Primary Tumor Site	Specimen Site (anatomical location)	Most Recent Specimen ☐ Yes ☐ No
Specimen Collection Location (Place of Service) ☐ Hospital Inpatient: Discharge Date _____ ☐ Hospital Outpatient: Discharge Date _____ ☐ Office/ASC ☐ Other: _____		
Facility Name Where Procedure Performed		Collection Date & Time (DD/MM/YYYY)
Specimen/Block ID#(s)		Date Removed from Storage (DD/MM/YYYY)

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

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™ 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™ (LDT)**

☐ *Add* MGMT by pyrosequencing for glioma cases

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

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, and (v) Caris' disclosure of testing results and information to third-party payers in connection with such testing.

Authorized Provider Signature:

Provider Name (Print):

Date (DD/MM/YYYY):

FINAL REPORT WILL BE DELIVERED IN ENGLISH. PLEASE SEE THE REVERSE FOR PATIENT CONSENT REQUIREMENTS AND OPTIMAL SPECIMEN REQUIREMENTS. TERMS AND CONDITIONS APPLY.

Test Descriptions

The biomarkers included in the options below may change from time to time. Before ordering, please refer to www.CarisLifeSciences.com 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 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. MGMT by pyrosequencing for glioma cases can be added to results.
	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™	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.

Specimen Requirements for Next-Generation Sequencing

SPECIMEN TYPE	SPECIMEN REQUIREMENTS
Tissue	• **MI Profile™:** 20% tumor nuclei, TNA extraction with ≥25 ng of DNA, Formalin-based fixatives preferred, Non-decalcified tissue preferred • **MI Tumor Seek Hybrid™ (LDT):** 20% tumor nuclei, TNA extraction with ≥25 ng of DNA, Formalin-based fixatives preferred, Non-decalcified tissue preferred

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 00 800 12 12 30 30.

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™ (LDT):** 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% 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.

Acknowledgment of Consent

By submitting this requisition, you, as the patient's physician, represent and verify that the patient has provided clear, unambiguous and explicit consent to send the patient's specimen and sensitive medical and other personal information to Caris Life Sciences, and to transfer that information to the United States for processing. Additionally, you represent that, as applicable to provisioning of this service, you and your office have complied with all applicable national and local privacy requirements and regulations.

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.

Important Treatment Note

The results for biomarkers tested under this requisition will be provided in a report associating one or more treatment agents to biomarkers based on published medical evidence, which may include published studies performed in the tumor type present in the tested sample or derived from a different tumor type. Decisions regarding care and treatment should not be based solely on selection of a test such as this test or the information provided related to this requisition. Decisions on patient care and treatment must be based on the treating physician's independent medical judgment, taking into consideration all relevant patient information, such as family history, physical examinations, results of other diagnostic tests, and patient preferences, and in accordance with the applicable standard of care. The selection of any or none of the matched agents is ultimately and solely in the discretion of the treating physician. Physician or practitioner hereby acknowledges and agrees to comply with any local, state/provincial, or national laws or regulations, rules or order of any governmental body, having jurisdiction over activities considered under this requisition.

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