International Tumour Profiling Requisition

Complete and fax or e-mail requisition with copy of pathology report to 00 800 12 12 32 32 or 00 41 21 533 53 01 or **InternationalSupport@CarisLS.com**.
The pathology report must bear the name of the originating institution and be stamped "controlled copy."
Please send the original copy of the requisition with the specimen.

CARIS LIFE SCIENCES

TREATING PHYSICIAN INFORMATION

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

PATIENT INFORMATION

Last Name	First Name	Initial
Date of Birth (dd/mm/yyyy)	Gender ☐ Male ☐ Female	
Address		
City	Country	Postal Code
Phone	Email Address	

PATHOLOGY INFORMATION *(Include a copy of the pathology report)*

Institution/Hospital Name	Pathologist Name		
Institution/Hospital Address	City	Country	Postal Code
Phone	Fax	Return Specimen Block To: ☐ Pathology ☐ Ordering Physician ☐ Caris to Archive *Return addresses must be provided above in order to return block*	

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)*

Primary Tumour Site		Shipment Tracking #
Specimen Site	Specimen/Block ID#(s)	Date & Time of Collection ☐ AM ☐ PM
Specimen Type(s): ☐ FFPE Block ☐ Unstained Slides ☐ Fresh Tissue in Formalin Solution *(contact international customer support prior to shipping)*		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.CarisMolecularIntelligence.com/profiling-menu, to view the definitive list of available biomarkers and the specific biomarkers analyzed by tumor type.***

TUMOR PROFILING OPTIONS *(Choice required)*

☐ **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 (DNA mutations, copy number alterations, insertions/deletions, genomic signatures: MSI, TMB), whole transcriptome sequencing (RNA fusions and variant transcripts), pyro sequencing, IHC, *in situ* hybridization.

☐ **MI Tumor Seek™**

NGS analysis of DNA for mutations, copy number alterations, insertions/deletions, genomic signatures (MSI, TMB), and whole transcriptome sequencing for RNA fusions and variant transcripts.

Add Immuno-Oncology IHC biomarkers:
☐ PD-L1 ☐ MMR (MLH1, MSH2, MSH6, PMS2)

☐ If the specimen is insufficient to perform the ordered tests, please proceed with limited testing recommended for this tumor type (available online at www.CarisMolecularIntelligence.com/profiling-menu).

SPECIAL INSTRUCTIONS

PLEASE SHARE A COPY OF THE FINAL REPORT WITH:

☐ Pathology ☐ Other Physician *(please specify)*: _____ Email: _____

Attestation: *This requisition constitutes an order for molecular testing from Caris MPI, 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 or Practitioner Signature**	**Print Name**	**Date**

FINAL REPORT WILL BE DELIVERED IN ENGLISH. PLEASE SEE THE REVERSE FOR PATIENT CONSENT REQUIREMENTS AND OPTIMAL SPECIMEN REQUIREMENTS.
Terms and conditions apply.

Specimen must be sent to Caris Life Sciences, 4610 South 44th Place, Phoenix AZ 85040, USA / CLIA 03D1019490 / CAP 7195577 / ISO 15189:2012
Customer Services Phone: 00 800 12 12 30 30 or 00 41 21 533 53 00 / Fax: 00 800 12 12 32 32 or 00 41 21 533 53 01 / E-mail: InternationalSupport@CarisLS.com

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.

For physicians and/or offices established in the European Economic Area, you and/or your office(s) (as applicable) agree that this engagement incorporates by reference the European Commission Standard Contractual Clauses for the Transfer of Personal Data to Processors Established in Third Countries (2010/87/EU), where Caris is "data importer," each of you and/or your office(s) are the "data exporter," the personal data processing is as described herein to provide the services requested (including as necessary for invoicing, debt collection, anonymization/de-identification, and as otherwise required by law), and the security measures are that Caris has reasonable technical, administrative and organizational security measures.

Office Checklist for Caris Molecular Intelligence

- ☐ Requisition (Completed, Signed and Dated)
- ☐ Pathology Report(s)
- ☐ Sufficient Tumour Specimen (Detailed Below)

Formalin Fixed Paraffin Embedded (FFPE) Samples

Sufficient tumour 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 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 • 5mm x 5mm x 4µm tissue/slide • **MI Profile**™: 25 slides • **MI Tumor Seek**™: 8 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 formalin fixed paraffin embedded • 18 gauge needle preferred, in 10% neutral buffered formalin.
Fine Needle Aspirate (FNA)	One (1) formalin fixed paraffin embedded block containing sufficient tumor
Malignant Fluid Cell Block	One (1) formalin fixed paraffin embedded cell block containing sufficient tumor (20% or more tumor nuclei).
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

Sufficient tumour must be present to complete all analysis. **Due to shipment times, contact customer services at 00 800 12 12 30 30 prior to biopsy of fresh tissue.**

SPECIMEN TYPE	SPECIMEN REQUIREMENTS
Fresh Tissue	Two (2) or more samples with a maximum thickness of ~3mm (height, width, length) and submit in 10% neutral buffered formalin. **Please do NOT send specimen larger than the recommended size.**
Core Needle Biopsy	Four to six (4-6) biopsies in 10% neutral buffered formalin.
Bone/Bone Metastasis	Two (2) or more samples with minimum thickness of 3mm (height, width, length) and submit in 10% neutral buffered formalin **(DO NOT DECALCIFY)**
Malignant Fluid	Maximum of 120ml malignant fluid, and submit mixed with a minimum of 120ml 10% neutral buffered formalin.

Insufficient Specimen Quantity – Prioritisation of Tests

In the event that a specimen is received with an insufficient quantity of tissue or insufficient percent tumor required to perform the entire profile or individual tests indicated on the requisition, Caris Life Sciences will fax the ordering physician the proposed list of tests. The physician may amend this 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.*

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 tumour type present in the tested sample or derived from a different tumour 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.

Specimen must be sent to Caris Life Sciences, 4610 South 44th Place, Phoenix AZ 85040, USA / CLIA 03D1019490 / CAP 7195577 / ISO 15189:2012
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