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 **EUCustomerServices@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 Nr.	Fax Nr.	

PATIENT INFORMATION

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

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

Institution/Hospital Name	Pathologist Name		
Institution/Hospital Address:	City	Country	Postal Code
Phone Nr:	Fax Nr:	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 Services 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
Tissue Type(s): ☐ FFPE Block ☐ Unstained Slides ☐ Fresh Tissue in Formalin Solution *(contact international customer services prior to shipping)*		Duration of Fixation (FFPE Blocks)

CARIS MOLECULAR INTELLIGENCE TUMOUR PROFILING OPTIONS *(Choice Required)*

Select a service from the list below. The offerings below are updated frequently with the published evidence. ***The definitive list of biomarkers analyzed by tumour type, and list of available biomarkers for the corresponding options below can be found online at www.CarisMolecularIntelligence.com/profilemenu("Website").***

SERVICES

Solid tumour biomarker analysis for therapeutic decision support and clinical trials matching *(for details, visit www.CarisMolecularIntelligence.com/profilemenu)*

☐ **MI Profile™** Multiple platform biomarker analysis (IHC; CISH; FISH; Next-Generation Sequencing; Pyro Sequencing; Fragment Analysis; *see Website for list of biomarkers performed for the tumour type submitted)*	☐ **Next-Generation Sequencing Analysis *(NGS Only)*** Next-Generation Sequencing only analysis *(see Website for list of biomarkers)*

The biomarkers included in the services above may change from time-to-time. Before ordering testing services, please refer to the Website, www.CarisMolecularIntelligence.com/profilemenu, to view a link for each Service above that provides the most up-to-date listing of biomarkers that will be performed by tumour type for the options listed above.

PLEASE SHARE A COPY OF THE FINAL REPORT WITH:

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

Notice: *This requisition constitutes an order for services. I certify (a) that the services are medically indicated and necessary and will assist me in treating my patient, (b) that I maintain and will make available patient medical records documenting the foregoing, and (c) I have supplied information to the patient regarding testing and if required by law, the patient has given consent for testing to be performed.*	**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. Visit http://www.CarisLifeSciences.com/order-now/client-services/ to view the terms and conditions in full.

Specimen must be sent to Caris Life Sciences, 4610 South 44th Place, Phoenix AZ 85040, USA / CLIA 03D1019490 / CAP 7195577 / ISO 15189:2012 – 3531.01 International 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 EUCustomerServices@carisls.com.

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TN9034 / **Revision Date February 25, 2016**

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 (Complete and Signed)
☐ Pathology Report
☐ 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 Services at 00 800 12 12 30 30.

SPECIMEN TYPE	SPECIMEN REQUIREMENTS
Fixed Tissue	One (1) tumour-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, tumour cells will be excised by microdissection until a total area of at least 50mm^2 is obtained.
Unstained Slides	Unstained, positively charged, unbaked slides from one single, tumour-containing formalin fixed paraffin embedded block; 4 micron sections • MI Profile™ - 55 slides • Next-Generation Sequencing only - 15 slides Note: At least a 5mm x 5mm section of tissue per slide is required. For small biopsies (tissue area < 5 mm x 5 mm) please cut two sections per slide for at least one half of the slides to ensure sufficient material for molecular assays.
Core Needle Biopsy	Four to six (4-6) biopsies formalin fixed paraffin embedded • 18 gauge needle preferred
Fine Needle Aspirate (FNA)	One (1) formalin fixed paraffin embedded block containing sufficient tumour
Malignant Fluid Cell Block	One (1) formalin fixed paraffin embedded cell block containing sufficient tumour (20% or more tumour nuclei).
Bone/Bone Metastasis	One (1) formalin fixed paraffin embedded block of tumour (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 shipment 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.
Core Needle Biopsy	Four to six (4-6) biopsies • 18 gauge needle preferred
Bone/Bone Metastasis	Two (2) or more samples with maximum thickness of 3mm (height, width, length) and submit in 10% neutral buffered formalin **(DO NOT DECALCIFY)**

Insufficient Specimen Quantity – Prioritisation of Tests

In the event that a specimen is received with an insufficient quantity of tissue or insufficient percent tumour 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 72 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 – 3531.01 International
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 EUCustomerServices@carisls.com.

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