International Tumour Profiling Requisition

Complete and fax or e-mail requisition with copy of pathology report to +800 12 12 32 32 or +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. All fields marked with an asterisk (*) are required.

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: _____

SPECIMEN INFORMATION *Include a copy of the pathology report.*

* Primary Tumour Site		Shipment Tracking #
* Specimen Site	* Specimen/Block ID#(s)	Date & Time of Collection (Formalin Vials) / / AM PM
Tissue Type(s): ☐ FFPE Block ☐ Unstained Slides		Duration of Fixation (FFPE Blocks)

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

Select a service from the list below. See reverse side for profile details. The offerings below are updated frequently with the published evidence. ***While every attempt is made to keep this printed requisition current, the definitive list of biomarkers should be verified on-line before ordering at www.CarisLifeSciences.eu/profilemenu.***

SERVICES

Solid tumour biomarker analysis for therapeutic decision support and clinical trials matching (see reverse for profile details).

Helpful when:

- treating aggressive, rare or refractory cancers
- looking for clinical trial opportunities

☐ **MI Profile™** Multiple platform biomarker analysis (IHC, CISH, FISH, FA, Next-Gen., Pyro and Sanger Sequencing)	☐ **Next-Generation Sequencing Analysis – *Only*** 46-gene profile by Next-Generation Sequencing	☐ **MI Profile™ Excluding Next-Generation Sequencing** Multiple platform biomarker analysis *excluding* Next-Gen. Sequencing (IHC, CISH, FISH, FA, Pyro and Sanger Sequencing)

ADDITIONAL SERVICES

Pathology Consult – Perform a pathology review/consult on the specimen submitted. ☐ Yes

Clinical Trials Connector™ – The MI Profile™ report includes information on relevant clinical trials. To decline the service, check box. ☐ Do Not Provide Information on Clinical Trials

PLEASE SHARE A COPY OF THE FINAL REPORT WITH:

☐ Pathology ☐ Other *(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 SPECIMEN REQUIREMENTS.

Terms and conditions apply. Visit www.CarisLifeSciences.eu/tumour-profiling-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: +800 12 12 30 30 or +41 21 533 53 00 / Fax +800 12 12 32 32 or +41 21 533 53 01 / E-mail EUCustomerServices@carisls.com.

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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 you and your office have abided by all EU, national and local privacy requirements and regulations related to this service.

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Profile Menu

The profile menus are updated frequently with the published evidence. ***While every attempt is made to keep this printed requisition current, the definitive list of biomarkers should be verified on-line before ordering at www.CarisLifeSciences.eu/profilemenu. Tests may vary if insufficient tumour samples are submitted.*** Please refer to the specimen requirements below for more information.

	IHC	FISH / CISH	Mutational Analysis	
			Next-Generation Sequencing	Other
MI Profile™ **MI Profile™ Excluding Next-Generation Sequencing** will not include the Next Gen. Sequencing genes listed below.	AR, cMET, EGFR *(H-score; NSCLC only)*, EGFR *(excluding NSCLC)*, ER, ERCC1 *(ovarian only)*, HER2, MGMT *(excluding glioma)*, MLH1 (CRC only), MSH2 *(CRC only)*, MSH6 *(CRC only)*, PD-1, PD-L1, Pgp, PMS2 *(CRC only)*, PR, PTEN, RRM1, SPARCm, SPARCp, TLE3, TOP2A *(excluding breast)*, TOPO1, TS, TUBB3	1p19q* *(glioma only)*, cMET*, HER2*, TOP2A* *(breast only)*, ALK* *(NSCLC only)*, ROS1* *(NSCLC only)*	*See Next-Generation Sequencing Genes below. (MI Profile excluding Next-Gen. Sequencing will not include the genes listed below)*	EGFRvIII *(Frag. Analysis; glioma only)*, IDH2 *(SangerSeq; glioma only)*, MGMT-Me *(PyroSeq; glioma only)* MSI *(Frag. Analysis; CRC only)*

Next-Generation Sequencing Analysis									
MI Profile™ Next-Generation Sequencing Genes							Additional Next-Generation Sequencing Genes (excluded from MI Profile™)		
ABL1	BRCA1*	EGFR	GNA11	JAK2	MPL	PTEN	CDH1	NPM1	STK11
AKT1	BRCA2*	ERBB2 (HER2)	GNAQ	KDR (VEGFR2)	NOTCH1	RET	ERBB4	PTPN11	
ALK	BRAF	FGFR1	GNAS	cKIT	NRAS	SMO	FBXW7	RB1	
APC	CSF1R	FGFR2	HRAS	KRAS	PDGFRA	TP53	HNF1A	SMAD4	
ATM	CTNNB1	FLT3	IDH1	cMET	PIK3CA	VHL	JAK3	SMARCB1	

In certain instances, some biomarkers included in the profiles listed above will not associate with commercially available cancer therapies or clinical trials.

** Assay may be performed by an external reference laboratory.*

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 +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, tumor cells will be excised by microdissection until a total area of at least 50mm2 is obtained. Tumour cells will be excised by microdissection from successive five (5) micron sections of the block until a total area of at least 15 mm^2 is obtained for both the MI Profile panel.
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
Unstained Slides	Unstained, positively charged, unbaked slides from one single, tumour-containing formalin fixed paraffin embedded block; 5 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.
Malignant Fluid	One (1) formalin fixed paraffin embedded cell block containing sufficient tumour.

Formalin Samples

Sufficient tumour must be present to complete all analysis. If you have any questions, please contact Customer Services at +800 12 12 30 30.

SPECIMEN TYPE	SPECIMEN REQUIREMENTS
Fresh Tissue	Two (2) or more samples with a minimum 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 minimum 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 email 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 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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