

# 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](mailto: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.

TREATING PHYSICIAN INFORMATION		PATIENT INFORMATION		
* Office/Facility Name	Caris Account Number/Distributor	* Last Name	* First Name	Initial
* Ordering Physician	Physician Email Address	* Address		
* Address		* City	* Country	* Postal Code
* City	* Country	* Postal Code	* Date of Birth (dd/mm/yyyy)	
* Phone Nr.	Fax Nr.	* Gender <input type="checkbox"/> Male <input type="checkbox"/> 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: <input type="checkbox"/> Pathology <input type="checkbox"/> Ordering Physician <input type="checkbox"/> Caris to Archive <i>Return addresses must be provided above in order to return block</i>		

BILLING INFORMATION	
<input type="checkbox"/> <b>Self-pay:</b> Payment is required before testing starts. Caris Customer Services will contact the patient directly to agree payment terms.	
<input type="checkbox"/> <b>Health Insurance:</b> A reimbursement request has been sent to patient's health insurance. Insurance Company: _____ Policy # _____ Pre-Authorisation / Authorisation #: _____ (if available)	
<input type="checkbox"/> <b>Hospitals/Clinics:</b> Institution will be billed after testing has been performed.	
<input type="checkbox"/> <b>Other,</b> please specify: _____	

SPECIMEN INFORMATION Include a copy of the pathology report.	
* Primary Tumour Site	Shipment Tracking #
* Specimen Site	* Specimen/Block ID#(s)
Tissue Type(s): <input type="checkbox"/> FFPE Block <input type="checkbox"/> Unstained Slides	Date & Time of Collection (Formalin Vials) / / AM PM Duration of Fixation (FFPE Blocks)

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

Select a service or individual assay(s) to be performed from the list below. See reverse side for profile details. The MI Profile panel is 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](http://www.CarisLifeSciences.eu/profilemenu).**

SERVICE	INDIVIDUAL ASSAY(S)				
<input type="checkbox"/> <b>MI Profile™</b> Multi-platform, solid tumour biomarker analysis for therapeutic decision support and clinical trials matching (see reverse for profile details), includes next generation sequencing (NGS) Helpful when: <ul style="list-style-type: none"> <li>• treating aggressive, rare or refractory cancers</li> <li>• looking for clinical trial opportunities</li> </ul>	<table border="0"> <tr> <td> <b>IHC</b>  <input type="radio"/> AR  <input type="radio"/> cMET  <input type="radio"/> EGFR  <input type="radio"/> ER  <input type="radio"/> ERCC1  <input type="radio"/> H3K36me3 (kidney only)  <input type="radio"/> HER2  <input type="radio"/> MGMT  <input type="radio"/> PBRM1  <input type="radio"/> (kidney only)  <input type="radio"/> PD-1                             </td> <td> <input type="radio"/> PD-L1  <input type="radio"/> Pgp  <input type="radio"/> PR  <input type="radio"/> PTEN  <input type="radio"/> RRM1  <input type="radio"/> SPARCm  <input type="radio"/> SPARCp  <input type="radio"/> TLE3  <input type="radio"/> TOPO1  <input type="radio"/> TOP2A  <input type="radio"/> TS  <input type="radio"/> TUBB3                             </td> <td> <input type="radio"/> Mismatch Repair*                      (includes 4 IHCs below)  <input type="radio"/> MLH1  <input type="radio"/> MSH2  <input type="radio"/> MSH6  <input type="radio"/> PMS2  <b>FISH or CISH</b>  <input type="radio"/> 1p19q (glioma only)  <input type="radio"/> ALK  <input type="radio"/> cMET  <input type="radio"/> EGFR  <input type="radio"/> MDM2  <input type="radio"/> HER2  <input type="radio"/> ROS1  <input type="radio"/> TOP2A                             </td> <td> <b>Mutational Analysis</b>  <input type="radio"/> Solid Tumour Cancer Service (46 genes, NGS)  <input type="radio"/> BRAF (cobas® PCR)  <input type="radio"/> EGFRvIII (Fragment Analysis)  <input type="radio"/> IDH2 (SangerSeq)  <input type="radio"/> MGMT-Me (PyroSeq)  <input type="radio"/> MSI* (Fragment Analysis)  <input type="radio"/> Individual Next-Generation Sequencing Genes (List the genes to be reported. See reverse for gene list):                      _____                      _____                             </td> </tr> </table> <p><small>*performed for CRC and endometrial carcinomas</small></p>	<b>IHC</b> <input type="radio"/> AR <input type="radio"/> cMET <input type="radio"/> EGFR <input type="radio"/> ER <input type="radio"/> ERCC1 <input type="radio"/> H3K36me3 (kidney only) <input type="radio"/> HER2 <input type="radio"/> MGMT <input type="radio"/> PBRM1 <input type="radio"/> (kidney only) <input type="radio"/> PD-1	<input type="radio"/> PD-L1 <input type="radio"/> Pgp <input type="radio"/> PR <input type="radio"/> PTEN <input type="radio"/> RRM1 <input type="radio"/> SPARCm <input type="radio"/> SPARCp <input type="radio"/> TLE3 <input type="radio"/> TOPO1 <input type="radio"/> TOP2A <input type="radio"/> TS <input type="radio"/> TUBB3	<input type="radio"/> Mismatch Repair* (includes 4 IHCs below) <input type="radio"/> MLH1 <input type="radio"/> MSH2 <input type="radio"/> MSH6 <input type="radio"/> PMS2 <b>FISH or CISH</b> <input type="radio"/> 1p19q (glioma only) <input type="radio"/> ALK <input type="radio"/> cMET <input type="radio"/> EGFR <input type="radio"/> MDM2 <input type="radio"/> HER2 <input type="radio"/> ROS1 <input type="radio"/> TOP2A	<b>Mutational Analysis</b> <input type="radio"/> Solid Tumour Cancer Service (46 genes, NGS) <input type="radio"/> BRAF (cobas® PCR) <input type="radio"/> EGFRvIII (Fragment Analysis) <input type="radio"/> IDH2 (SangerSeq) <input type="radio"/> MGMT-Me (PyroSeq) <input type="radio"/> MSI* (Fragment Analysis) <input type="radio"/> Individual Next-Generation Sequencing Genes (List the genes to be reported. See reverse for gene list): _____ _____
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ADDITIONAL SERVICES	
<input type="checkbox"/> <b>Pathology Consult</b> – Perform a pathology review/consult on the specimen submitted. <input type="checkbox"/> Yes	
<input type="checkbox"/> <b>Clinical Trials Connector™</b> – The MI Profile™ report includes information on relevant clinical trials. To decline the service, check box. <input type="checkbox"/> Do Not Provide Information on Clinical Trials	

Please share a copy of the final report with:	
<input type="checkbox"/> Pathology <input type="checkbox"/> Other (please specify) _____	Email: _____

<i>NOTICE: This requisition constitutes an order for services. I certify that the services are medically indicated and necessary, and that they will assist me in treating my patient.</i>	<b>Physician or Practitioner Signature</b>	Print Name	Date
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**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](http://www.CarisLifeSciences.eu/tumour-profiling-services) to view the terms and conditions in full.



## Profile Menu

The MI Profile panel is 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](http://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
<b>MI Profile™</b>	AR, cMET, EGFR ( <i>H-score; NSCLC only</i> ), EGFR ( <i>excluding NSCLC</i> ), ER, ERCC1 ( <i>ovarian only</i> ), HER2, MGMT ( <i>excluding glioma</i> ), MLH1 ( <i>CRC only</i> ), MSH2 ( <i>CRC only</i> ), MSH6 ( <i>CRC only</i> ), PD-1, PD-L1, Pgp, PMS2 ( <i>CRC only</i> ), PR, PTEN, RRM1, SPARCm, SPARCp, TLE3, TOP2A ( <i>excluding breast</i> ), TOPO1, TS, TUBB3	1p19q* ( <i>glioma only</i> ), cMET*, HER2*, TOP2A* ( <i>breast only</i> ), ALK* ( <i>NSCLC only</i> ), ROS1* ( <i>NSCLC only</i> )	See MI Profile Next-Generation Sequencing Genes below.	
			BRAF ( <i>PCR, melanoma only</i> ), EGFRvIII ( <i>Frag. Analysis; glioma only</i> ), IDH2 ( <i>SangerSeq; glioma only</i> ), MGMT-Me ( <i>PyroSeq; glioma only</i> ) MSI ( <i>Frag. Analysis; CRC only</i> )	

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

MI Profile includes biomarkers associated with commercially available cancer therapies or clinical trials for the same or different tumor type. Other biomarkers outside MI Profile are also available; and, are known to be associated with cancer, but may have other clinical utilities including: predictive, prognostic or diagnostic associations.

\* 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 50mm <sup>2</sup> 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 <sup>2</sup> 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 ( <b>DO NOT DECALCIFY</b> )

## 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.