International Tumour Profiling Requisition – EU

Submit completed requisition with a copy of pathology report to **InternationalSupport@CarisLS.com**.
The pathology report must bear the name of the originating institution and be stamped "controlled copy."

CARIS LIFE SCIENCES

TREATING PHYSICIAN INFORMATION

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

PATIENT INFORMATION

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

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.

☐ **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)*

Diagnosis	Clinical Stage ☐ Stage I ☐ Stage II ☐ Stage III ☐ Stage IV	Primary Tumour Site
Specimen Site	Specimen Type(s): ☐ FFPE Block ☐ Unstained Slides	Fixation Details: Cold ischemic time ≤ 1 hour: ☐ Yes ☐ No ☐ Unknown; 10% neutral buffered formalin: ☐ Yes ☐ No ☐ Unknown; Fixation duration 6 – 72 hours: ☐ Yes ☐ No ☐ Unknown
Date & Time of Collection ____ ____ _____ ____ ____ ☐AM ☐PM	Specimen ID	

CARIS MOLECULAR PROFILING

To order, please indicate below. ***Before ordering, please refer to www.CarisLifeSciences.com/profiling-menu for assay details, technical specifications and gene list.***

TUMOUR PROFILING *(selection required)*

☐ **MI Tumor Seek™**

MI Exome™ (whole exome sequencing) analysis of DNA for mutations, copy number alterations, insertions/deletions, genomic signatures (HLA, LOH, MSI, TMB), and MI Transcriptome™ (whole transcriptome sequencing) for RNA fusions and variant transcripts. Caris FOLFIRSTai™ will be performed for metastatic colorectal adenocarcinoma cases.

☐ **Caris GPSai™**

Cancer type similarity assessment consisting of algorithmic analyses of the genomic (DNA) and transcriptomic (RNA) characteristics of the tumor as compared to more than 20 distinct tumor types in the Caris database. *Only available if MI Tumor Seek is ordered.*

SPECIAL INSTRUCTIONS

SHARE A COPY OF THE FINAL REPORT WITH:

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

Physician/Authorized Provider Signature	Print Name	Date	***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.*

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

4610 South 44th Place, Suite 100 / Phoenix, Arizona 85040 / CLIA 03D1019490 / CAP 7195577 / ISO 15189:2012
Customer Support 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 / Email: InternationalSupport@CarisLS.com

TN9034 v4 / **Revision Date May 19, 2022**

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. In addition, you represent and verify that information regarding Caris' molecular profiling was provided during an interview with the patient in a comprehensive, concise, clear, relevant, and understandable manner, as required by Regulation (EU) 2017/746, and the patient had an opportunity to ask questions, and all of their questions were answered.

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 Testing

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

Formalin Fixed Paraffin Embedded (FFPE) Samples

Sufficient tumour (>20% tumour 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) 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 60 mm^2 is obtained.
Unstained Slides	Unstained, positively charged, unbaked slides from one single, tumour-containing formalin fixed paraffin embedded block; 4 micron sections • Tumour content: ≥20% tumour nuclei • **MI Tumor Seek™**: 10 slides Note: Specimens with a smaller tumour area may require additional specimen to be submitted. If the tumour area per slide exceeds 25mm^2, fewer slides are needed for testing.
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 tumour. **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 tumour (20% or more tumour nuclei). **Please do NOT use non-formalin-based fixatives, including alcohol-based fixatives.**
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.

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.

CE IVD

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Patient Notice and Consent for Molecular Profiling and Data Transfer

European Economic Area and Switzerland

This notice and consent form ("Notice") provides you information on how Caris MPI, Inc. d/b/a Caris Life Sciences ("Caris"), a specialized clinical laboratory operating in Phoenix, Arizona, USA, will process your personal data.

Use, processing, transfer and disclosure of your specimen and personal data

Caris will process your personal data set for the purposes of tumor molecular profiling (Caris Molecular Intelligence®). As part of your care, your healthcare provider has recommended that a biological specimen from you be assessed to provide a unique molecular profile. The "molecular profile" for an individual's tumor or cancer consists of certain DNA, RNA or proteins that are referred to as "biomarkers," which may be present in cells, tissue or blood samples obtained from you. Different biomarkers associate with different therapeutics or drugs. Caris performs a series of tests to identify the unique biomarkers in your tumor, and this information may in turn help your healthcare provider with additional options to treat your cancer based on its molecular profile (this is commonly referred to as "targeted therapy" or "personalized treatment"). The molecular profiling results and interpretations are intended to supplement and not be a substitute for your physician's medical judgment or advice. There is no guaranteed benefit from having such testing performed.

Your specimen (biopsy, tissue or blood sample) along with your personal data will be sent by your healthcare provider, acting as the data controller of such data, to Caris in the United States where the tumor profiling tests are performed. As the data controller of your personal data, your healthcare provider is required by the GDPR to provide certain notices to you.

Caris acts as data processor (or equivalent term under local law) for your personal data. As a data processor for your healthcare provider, Caris is restricted both by applicable Data Protection Laws[1] and by our contract with your healthcare provider as to how we handle your personal data. Caris will process your specimen and your personal data in its laboratories in the United States. The data protection laws of the United States may not be equivalent to those in your country of residence. The European Commission has not issued a decision that the Data Protection Laws of the United States provide an adequate level of protection for personal data. However, we take steps to ensure that your personal data continues to be treated in accordance with this Notice and the Data Protection Laws regardless of where your personal data are processed.

Certain personal data may also be transferred or provided to Caris' offices in your region who coordinate with your healthcare provider, Caris distributors in your region or both in order to perform the molecular profile testing. For more information on regional office location please visit www.carislifesciences.com or ask your healthcare provider which regional offices and Caris distributors will receive your personal data.

Caris will utilize your personal data in furtherance of performing the molecular profile tests on your specimen and providing the resulting data Molecular Data ("Molecular Data") to you, your healthcare provider, or other recipients as authorized by you. Caris may also process, transfer and disclose your personal data or Molecular Data for the following additional purposes and to the following additional recipients:

- the distributor of Caris services in your region, so that the treatment and services you receive may be billed to and payment may be collected from you, your insurance company, or a third party you designate;
- operational reasons as well as to review the quality of our services and to evaluate the performance of our staff; and
- as otherwise required by applicable laws in your region and the U.S.

Caris may use leftover specimen materials, molecular profiling information and clinical information, so long as such materials and information are de-identified and do not contain any of your personal data, for research, education and training purposes to optimize the different tests and improve healthcare operations, when permitted under applicable laws and regulations. Your personal data (i.e., your name, patient number, date of birth, gender, address, medical history and pathology report) will not be disclosed or otherwise used in this context without your specific additional consent.

Caris processes the following categories of your personal data exclusively on the basis of your consent:

- name;
- address;
- patient number;
- date of birth;
- gender;
- name and address of physicians, hospitals, and other healthcare providers involved in the treatment of the patient's tumor or cancer;
- data on patient's relevant treatment history and pathology reports;
- DNA, RNA, protein, and other molecular data; and
- other data required for the treatment and analysis of tumors or cancer.

For the purposes set out above, Caris will transfer your personal data to the following recipients:

- IT service providers that Caris uses;
- companies that are part of Caris' corporate group;
- your healthcare provider.

By signing at the bottom of this document, you consent to the collection (if necessary), processing, use and transfer of your specimen and personal data by your healthcare provider and by Caris on behalf of your healthcare service provider, as described herein.

Specimen and personal data provided by your healthcare provider to Caris

Your healthcare provider will provide Caris with your specimen, as well as your personal and medical information (i.e., your name, patient number, date of birth, gender, address, medical history and pathology report) in order for Caris to perform testing. The data resulting from Caris' performance of the molecular profile testing based on your specimen will be provided to your healthcare provider upon completion of testing. Your Molecular Data is also considered to be personal data to the extent that it can be associated with you by the use of additional information (such as by your name or patient identification number being listed on a report). Caris has implemented reasonable technical, administrative and organizational security measures to comply with applicable Data Protection Laws to protect your specimen, personal data, and Molecular Data from unauthorized or inadvertent disclosure or accidental loss or destruction.

Rights to your personal data

Your healthcare provider is the data controller with respect to your personal data. Besides the attached HCP Data Protection Notice, your healthcare provider may provide you with additional data protection notices and possibly with consent forms in connection with your health care more generally. You may have the rights to access, correct, restrict, delete and receive a copy of your personal data held by or on behalf of your healthcare provider. For further information on how your personal data is used, how security is maintained and to exercise your various data subject rights, please contact your healthcare provider. In the unlikely event that you do not receive a response from your healthcare provider because they are no longer in existence (for example, due to the healthcare provider's corporate entity being wound up or dissolved), you may contact us directly at legal@carisls.com.

Consent

I have read and I understand the information provided in this Patient Notice and Consent for Molecular Profiling and Data Transfer (including its attachments), have had all of my questions about it answered, and hereby voluntarily provide my express consent to the collection, use, processing, transfer and disclosure of my specimen and personal data (including medical information and sensitive data) as described in this Patient Data Protection Consent for Molecular Profiling.

_____

Patient Name (printed)

_____ _____

Patient Signature **Date**

[1] Data Protection Laws shall mean: (i) the General Data Protection Regulation 2016/679 (the "GDPR:); (ii) any implementing, derivative or related legislation of any member state in the European Economic Area of the GDPR; and (iii) the Swiss Federal Act on Data Protection 1992 (as amended) and any successor legislation thereto.

Your Healthcare Provider's Approved Data Protection Notice Regarding Caris' Molecular Profiling Services

Name of controller and contact details (including of data protection officer, if there is one)	You have received information concerning the name of the controller from your healthcare provider when you first became its patient, or through a subsequent communication from your healthcare provider. Your healthcare provider also will have provided information regarding whether it has a data protection office and how to contact that person either by a direct communication to you or via a publicly available listing such as on your healthcare provider's website.
Purposes of the processing	The purpose of the processing is to conduct molecular profile testing based on your tumor or other biological specimen and to provide a report to your healthcare provider upon completion of testing. That report will be used by your healthcare provider to make decisions about your health care.
Legal basis (also known as the "lawful basis") for the processing	The legal basis for the processing of your personal data comprising Molecular Data or other health or genetic information is that the processing is necessary processing for the purposes of medical diagnosis and/or the provision of health or social care or treatment on the basis of Union or Member State law or pursuant to contract with a health professional and subject to the conditions and safeguards set out in the GDPR. The legal basis for the processing of your billing-related information is the legitimate interest of the company (whether Caris or its distributors) that are contractually responsible for providing the services described in the Notice.
The legitimate interests of the controller or third party, where applicable	As described immediately above, your billing-related information is processed based on the legitimate interest of Caris or its distributors (depending on which entity is responsible for billing based on arrangements with your healthcare provider) in receiving payment for its services.
The categories of personal data concerned	The Caris molecular profiling services involve the use of the following categories of data: • Sensitive personal data: medical history, genetic information, pathology report • Personal data used to ensure your specimen and pathology report are correctly identified: name, patient number, date of birth, gender and possibly your address • Personal data used for billing purposes: name, address and other contact details that you have provided for this purpose
The recipients or categories of recipients of the personal data	Caris MPI, Inc. d/b/a Caris Life Sciences and its distributor in your region (list available at www.carislifesciences.com; specific details will be provided to you when your specimen is collected)
Transfer of your personal data outside of the European Economic Area (EEA), destination country, lack of a Commission adequacy decision for the country, and safeguards for the transfer	Your specimen and personal data will be transferred to Caris in the United States where the tumor profiling tests are performed. The USA does not have an adequacy decision from the European Commission, which means that the Commission does not deem the data protection laws of the USA to offer an adequate level of protection compared to the data protection laws of the EU. However, the USA does have data protection laws that protect health information, and Caris complies with those laws as well as the Data Protection Laws. Furthermore, Caris has committed to the safeguards described in the Patient Notice and Consent for Molecular Profiling and Data Transfer. Your healthcare provider (as the data controller) also has a written agreement in place with Caris or Caris' distributor (as the data processor) that meets the requirements of the GDPR. Further information about these safeguards is available upon request from your healthcare provider.
The period for which the personal data will be stored, or if a set period cannot be determined in advance, the criteria for determining the retention period	Your personal data will be stored by Caris for 50 years.
Your rights to access, correct, restrict or delete your personal data, and object to processing	The Data Protection Laws (including the GDPR) provide various rights to access, correct, restrict or delete one's personal data and to object to processing. These rights are subject to various limitations. To exercise any of these rights, please contact your healthcare provider's data protection officer or other designated contact, details of which have been provided to you separately in the context of the services that your healthcare provider provides to you regarding your general health care.
The right to lodge a complaint with a supervisory authority	You have the right to file data protection complaints with your national (or in some countries, regional) data protection authority.
Absence of statutory or contractual requirement to provide any personal data	There is no statutory or contractual requirement or other obligation to provide any personal data to your healthcare provider, but failing to do so means that you will not be able to have your specimen processed by Caris and you will not receive a molecular profile of your tumor or other specimen.

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