

# Molecular Profiling Test Request Form

For Project ID Use Only



For fastest order processing, order online at [portal.caris.ai](https://portal.caris.ai)

Phone: (888) 979-8669 | Fax: (866) 479-4925 | Email: [CustomerSupport@CarisLS.com](mailto:CustomerSupport@CarisLS.com)

Incomplete or missing information may result in delayed testing.

| TREATING PHYSICIAN INFORMATION *Indicates a required field. |                      |          | PATIENT INFORMATION *Indicates a required field. |  |             |                                                                          |
|-------------------------------------------------------------|----------------------|----------|--------------------------------------------------|--|-------------|--------------------------------------------------------------------------|
| *Name                                                       |                      | *NPI     | *Last Name                                       |  | *First Name | MI                                                                       |
| *Physician Email                                            | *Office Contact Name |          | In-Office Medical Record Number                  |  | *DOB        | *Biological Sex<br><input type="checkbox"/> M <input type="checkbox"/> F |
| *Office/Hospital Name                                       |                      | *Address | *Address                                         |  |             | Apt.                                                                     |
| *City                                                       | *State               | *Zip     | *City                                            |  | *State      | *Zip                                                                     |
| *Phone                                                      |                      | *Fax     | *Mobile Phone                                    |  | *Email      |                                                                          |

## MOLECULAR PROFILING TESTING OPTIONS *Test selection(s) required.*

For specimen requirement instructions and current profiling menu, please see technical specifications and tumor specific profiling on the Caris website.

| TISSUE-BASED TESTING                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | BLOOD-BASED TESTING                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <input type="checkbox"/> <b>MI Cancer Seek® (CDx) + IHCs and Additional Molecular Tests by Tumor Type</b><br><input type="checkbox"/> Include Caris GPSai® reporting for cancer type similarity assessment<br><input type="checkbox"/> <b>MI Cancer Seek® (CDx)</b><br><input type="checkbox"/> Add MGMT by pyrosequencing for glioma cases<br><input type="checkbox"/> Include Caris GPSai® reporting for cancer type similarity assessment<br><input type="checkbox"/> Add IHC Testing<br><input type="checkbox"/> CLDN18 <input type="checkbox"/> FOLR1 <input type="checkbox"/> HER2 <input type="checkbox"/> MET <input type="checkbox"/> MMR <input type="checkbox"/> PD-L1<br><input type="checkbox"/> PTEN <input type="checkbox"/> Other _____<br><i>If sample does not meet specimen requirements, the order will reflex to MI Tumor Seek Hybrid™ (LDT).</i><br><i>GPSai® for cancer type similarity assessment will be reported when information is sufficient to generate a result.</i> | <input type="checkbox"/> <b>Caris Assure®</b><br><input type="checkbox"/> Caris phlebotomy services requested<br><input type="checkbox"/> Exclude incidental germline results<br><input type="checkbox"/> Exclude DPYD results<br><input type="checkbox"/> Exclude UGT1A1 results<br><input type="checkbox"/> Does the patient have a history of:<br><input type="checkbox"/> Hematologic malignancy<br><input type="checkbox"/> MDS<br><input type="checkbox"/> Bone marrow/stem cell/solid organ transplant<br><input type="checkbox"/> None<br>Is tissue specimen from a recent procedure available?<br><input type="checkbox"/> Yes <input type="checkbox"/> No<br>Tissue testing resulted in Quantity Not Sufficient<br><input type="checkbox"/> Yes <input type="checkbox"/> No | Reflex this order to Caris Assure® if MI Cancer Seek® cannot provide complete results due to insufficient quantity, insufficient quality, or limited tissue (IHC-only results).<br><input type="checkbox"/> <b>Reflex to Caris Assure®</b><br><input type="checkbox"/> Caris phlebotomy services requested<br><input type="checkbox"/> Exclude incidental germline results<br><input type="checkbox"/> Exclude DPYD results<br><input type="checkbox"/> Exclude UGT1A1 results<br><input type="checkbox"/> Does the patient have a history of:<br><input type="checkbox"/> Hematologic malignancy<br><input type="checkbox"/> MDS<br><input type="checkbox"/> Bone marrow/stem cell/solid organ transplant<br><input type="checkbox"/> None |
| Pathology Services/<br>Specimen Storage Location _____<br><br>Address/Suite _____<br><br>City _____ State _____ ZIP _____<br><br>Phone _____ Fax _____                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | PLACE PATIENT ID/SPECIMEN LABEL HERE<br>(Blood Only)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |

## SPECIAL INSTRUCTIONS/ADDITIONAL PHYSICIAN TO BE COPIED (OPTIONAL)

Special Instructions

Additional Physician Name to be Copied

Facility Name

Additional Physician Email

## BILLING INFORMATION \*Indicates a required field. Attach the front and back of PRIMARY and SECONDARY insurance cards. Patient insurance/payment is REQUIRED to begin testing.

|                                                                      |                     |           |          |               |              |                          |                        |
|----------------------------------------------------------------------|---------------------|-----------|----------|---------------|--------------|--------------------------|------------------------|
| <input type="checkbox"/> Insurance <input type="checkbox"/> Self Pay | *Insurance Provider | *Policy # | *Group # | *Insured Name | *Insured DOB | *Relationship to Patient | *Prior Authorization # |
| <input type="checkbox"/> Direct/Client Bill # _____                  | *Primary            |           |          |               |              |                          |                        |
| <input type="checkbox"/> HMO/Referral # _____                        | Secondary           |           |          |               |              |                          |                        |
| <input type="checkbox"/> Other _____                                 |                     |           |          |               |              |                          |                        |

## CLINICAL/SPECIMEN INFORMATION \*Indicates a required field. Include a copy of the pathology report and medical records that support the need for testing.

|                                                      |                                                                                                                                       |                                                                                               |                                                                                                                                                                                                                                                                                              |                                                                                                                                               |
|------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------|
| *Primary ICD-10                                      | Clinical Stage<br><input type="checkbox"/> II<br><input type="checkbox"/> III<br><input type="checkbox"/> IV                          | Date of Original Diagnosis (MM/DD/YYYY)                                                       | Disease Status at Time of Testing (select all that apply)<br><input type="checkbox"/> Metastatic <input type="checkbox"/> Refractory<br><input type="checkbox"/> Recurrent <input type="checkbox"/> Unresectable<br><input type="checkbox"/> Relapsed <input type="checkbox"/> None of these | Patient is Seeking Further Treatment and is<br><input type="checkbox"/> Newly Diagnosed<br><input type="checkbox"/> Not Responding to Therapy |
| *Primary Tumor Site                                  |                                                                                                                                       | Facility Where Procedure Performed/Collected                                                  |                                                                                                                                                                                                                                                                                              |                                                                                                                                               |
| *Tissue Specimen Collection Date & Time (MM/DD/YYYY) | <input type="checkbox"/> Hospital Inpatient <input type="checkbox"/> Hospital Outpatient <input type="checkbox"/> Office/Non-Hospital | <input type="checkbox"/> Not yet discharged OR <input type="checkbox"/> Discharge date: _____ | Specimen Type(s)<br><input type="checkbox"/> FFPE Block <input type="checkbox"/> Unstained Slides<br><input type="checkbox"/> Formalin Fixative <input type="checkbox"/> Whole Blood                                                                                                         | Blood Sample Draw<br><input type="checkbox"/> Venous <input type="checkbox"/> Port                                                            |
| Date Tissue Sample Removed from Storage (MM/DD/YYYY) | *Tissue Specimen ID#(s)                                                                                                               |                                                                                               | Specimen Site (anatomical location)                                                                                                                                                                                                                                                          | *Blood Specimen Collection Date & Time (MM/DD/YYYY)                                                                                           |

## ADDITIONAL INFORMATION ON NEXT PAGE. PROVIDER SIGNATURE REQUIRED ON PAGE 2

| MI CANCER SEEK® FDA COMPANION DIAGNOSTIC INDICATIONS *Selection required.           |                                                                                                                           |                                                                            |
|-------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------|
| *INDICATIONS                                                                        | BIOMARKERS                                                                                                                | FDA-APPROVED THERAPY                                                       |
| <input type="checkbox"/> Breast Cancer                                              | PIK3CA (C420R; E542K; E545A, E545D [1635G>T only], E545G, E545K, Q546E, Q546R; and H1047L, H1047R, H1047Y)                | PIQRAY® (alpelisib)                                                        |
| <input type="checkbox"/> Colorectal Cancer (CRC)                                    | KRAS wild-type (absence of mutations in exons 2, 3, and 4) and NRAS wild-type (absence of mutations in exons 2, 3, and 4) | VECTIBIX® (panitumumab)                                                    |
|                                                                                     | BRAF V600E                                                                                                                | BRAFTOVI® (encorafenib) in combination with ERBITUX® (cetuximab)           |
| <input type="checkbox"/> Melanoma                                                   | BRAF V600E                                                                                                                | BRAF inhibitors approved by FDA*                                           |
|                                                                                     | BRAF V600E or V600K                                                                                                       | MEKINIST® (trametinib) or BRAF/MEK inhibitor combinations approved by FDA* |
| <input type="checkbox"/> Non-Small Cell Lung Cancer (NSCLC)                         | EGFR exon 19 deletions and exon 21 L858R alterations                                                                      | EGFR Tyrosine Kinase Inhibitors approved by FDA*                           |
| <input type="checkbox"/> Solid Tumors                                               | MSI-H                                                                                                                     | KEYTRUDA® (pembrolizumab), JEMPERLI® (dostarlimab-gxly)                    |
| <input type="checkbox"/> Endometrial Carcinoma                                      | Not MSI-H                                                                                                                 | KEYTRUDA® (pembrolizumab) in combination with LENVIMA® (lenvatinib)        |
| <input type="checkbox"/> If other indications for testing apply, please check here. |                                                                                                                           |                                                                            |

\*For the most current information about the device indications for the therapeutic products in this group, visit the FDA website for "[Device Indication for a Specific Group of Oncology Therapeutic Products](#)."

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| PHYSICIAN ATTESTATION OF MEDICAL NECESSITY *Indicates a required field.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |  |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--|
| <p>This requisition constitutes an order for molecular testing from Caris MPI, Inc. (Caris) 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 will make available patient medical records documenting the foregoing, and (d) I supplied information to the patient regarding this testing, explained the purpose of this testing to the patient, and obtained informed consent for (i) such testing, (ii) any analysis and reports related to such testing, (iii) Caris to retain testing results, samples and related information and analysis, (iv) Caris' use or disclosure (including to third parties) of deidentified information generated from such testing for general research and other purposes, (v) Caris' disclosure of testing results and information to third-party payers in connection with such testing, and (vi) for Caris to contact the patient regarding the testing.</p> <p>I further attest that if this order is for concurrent tissue and blood profiling, or if both are ordered within the same 30-day period, that both tests will assist me in treating my patient and is medically necessary based on several clinical factors, which may include, oncology guidelines support concurrent testing in this disease state, turnaround time for tissue-based testing may delay important treatment decisions, or the available tissue may not meet testing requirements, among others. Additionally, I will provide any requested medical records necessary to support concurrent testing.</p> <p>I have conferred with the treating provider and am ordering per his/her request for use in determining treatment options for their patient. By signing below, I certify that I am the ordering provider identified on this requisition or an individual expressly authorized to submit this requisition on behalf of the ordering provider, and that the ordering provider has authorized the requested testing.</p> |  |
| <p><b>*Authorized Provider Signature</b> <input type="checkbox"/> I have conferred with the treating provider and am ordering per his/her request for use in determining treatment options for their patient.</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |  |
| <p><b>*Provider Name (Print)</b></p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |  |
| <p><b>*Date</b></p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |  |

| TEST DESCRIPTIONS |                                                                         |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
|-------------------|-------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| TISSUE            | <b>MI Cancer Seek® (CDx)</b><br><i>Next-Generation Sequencing</i>       | MI Cancer Seek® is a NGS-based <i>in vitro</i> diagnostic device that uses total nucleic acid isolated from formalin-fixed paraffin-embedded tumor tissue specimens and a broad, multi-gene panel to detect several types of genomic alterations via a combined WES/WTS platform. MI Cancer Seek is intended as a companion diagnostic (CDx) to identify patients who may benefit from treatment with the targeted therapies listed in the Companion Diagnostic Indications table, in accordance with the approved therapeutic product labeling. MI Cancer Seek is available for adult and pediatric (ages 1+) patients. Additionally, MI Cancer Seek is intended to provide tumor mutational profiling to be used by qualified healthcare professionals in accordance with professional oncology guidelines for cancer patients with solid malignant neoplasms. Genomic findings other than those listed in the Companion Diagnostic Indications table are not prescriptive or conclusive for labeled use of any specific therapeutic product. See website for complete product information, including companion diagnostic indications and performance characteristics. |
|                   | <b>MI Tumor Seek Hybrid™ (LDT)</b><br><i>Next-Generation Sequencing</i> | MI Tumor Seek Hybrid™ is a NGS-based laboratory-developed test that uses WES/WTS to analyze DNA and RNA extracted from tumor tissue to detect multiple types of genomic alterations. Caris FOLFIRSTai® is performed for mCRC cases and Caris GPSai® is performed for CUP cases. MGMT by pyrosequencing for glioma cases can be added to results.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
|                   | <b>Caris GPSai®</b>                                                     | Caris GPSai® is a cancer type similarity assessment intended to help identify tumor of origin by matching a tumor's molecular signature to the Caris genomic and transcriptomic database. GPSai® for cancer type similarity assessment will be reported when information is sufficient to generate a result.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
|                   | <b>Caris FOLFIRSTai®</b>                                                | Caris FOLFIRSTai® is a chemotherapy response predictor that is intended to gauge a mCRC patient's likelihood of benefit from first-line FOLFOX+BV followed by FOLFIRI+BV, versus FOLFIRI+BV followed by FOLFOX+BV treatment. Caris FOLFIRSTai® is performed for mCRC cases.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |
| BLOOD             | <b>Caris Assure®</b>                                                    | Blood-based Whole Exome and Whole Transcriptome Sequencing for pathogenic and likely pathogenic tumor-derived, incidental germline, and incidental CH variant detection. Caris Assure® is intended for patients with previously diagnosed solid malignant neoplasms when tissue profiling is not feasible or when comprehensive genomic profiling is needed to inform therapy selection decisions and is to be used by qualified healthcare professionals. Not a replacement for comprehensive germline testing. Incidental pathogenic alterations are reported, including ACMG recognized cancer genes. Negative results do not imply that the patient does not harbor a germline mutation. Not intended for patients with a history of bone marrow, stem cell, or solid organ transplant.                                                                                                                                                                                                                                                                                                                                                                               |

## Checklist for Ordering

- ☐ Molecular Profiling Test Request Form (Completed, Signed and Dated)
- ☐ Insurance Information (Copy of Insurance Card Preferred)
- ☐ Patient Progress Note(s) / Medical Record(s)
- ☐ Demographics or Face Sheet
- ☐ Pathology Report if ordering MI Cancer Seek®
- ☐ Tumor Specimen if ordering MI Cancer Seek®
- ☐ Blood specimen if ordering Caris Assure®
- ☐ Patient Consent if ordering Caris Assure®

**Note: Customer Support may contact your office to obtain certain medical records that may be required by patient's insurance company (e.g. 90-day clinical history, physical exam, and additional notes, including: daily progress, treatment, doctors and office).**