Caris MI Clarity™ Test Request Form – International

For Project ID Use Only

Phone: 00 41 21 533 53 00 | Fax: 00 41 21 533 53 01 | Email: InternationalSupport@CarisLS.com
Please complete and return by fax or email. Incomplete or missing information may result in delayed testing.

CARIS LIFE SCIENCES

ORDERING PHYSICIAN INFORMATION **Indicates a required field.*

*Physician Name	Caris Account Number/Distributor	
Physician Email	Office Contact Name	
*Office/Hospital Name	*Address	
*City	*Country	*Postal Code
*Phone (include country code)	*Fax (include country code)	

PATIENT INFORMATION **Indicates a required field.*

*Last Name	*First Name		Middle Initial
In-Office Medical Record Number	*DOB (DD/MM/YYYY)	Biological Sex ☐ M ☑ F	Ethnicity
*Address			Apt.
*City	*Country		Postal Code
Mobile Phone (include Country Code)	Email		

TEST SELECTION *Selection required.*

☐ **Caris MI Clarity™**
Caris MI Clarity™ is an AI-powered breast cancer test designed to provide recurrence risk and treatment decision-support information in early-stage breast cancer (HR+/HER2-). The test analyzes digitized hematoxylin and eosin (H&E) whole-slide images together with clinicopathologic variables to generate **early distant recurrence (EDR)** risk (0–5 years) and **late distant recurrence (LDR)** risk (5–15 years). These probabilities are subsequently stratified into categorical risk groups (i.e., low vs. high risk). Results may also include assessment of potential benefit from chemotherapy and/or extended endocrine therapy to support personalized treatment decisions.

☐ **Caris MI Clarity™ – Late Distant Recurrence Only**
Select this option to receive the **late distant recurrence (LDR)** only result. Provides late (5-15 years) distant recurrence-risk assessment and extended endocrine therapy benefit information for eligible patients.

Reporting note: Premenopausal patients are only eligible to receive Early Distant Recurrence (EDR) results.

CLINICAL INFORMATION **Indicates a required field. Include a copy of the most recent progress notes.*

ICD-10 Code(s)	*Date of Original Diagnosis (DD/MM/YYYY)	*Primary Tumor/Specimen Site ☑ Breast	*Tumor Grade ☐ Low ☐ Intermediate ☐ High
*Menopausal Status at Time of Diagnosis ☐ Premenopausal ☐ Postmenopausal	*ER Status ☐ Positive ☐ Negative	*PR Status ☐ Positive ☐ Negative	*HER2 Status ☐ Positive – Ineligible ☑ Negative
*TNM Stage ☐ T1 ☐ T2 ☐ T3 | ☐ N0 ☐ N1 ☐ N2 ☐ N3 | ☐ M0 ☐ M1 – Ineligible		*Surgery Type ☐ Lumpectomy ☐ Mastectomy	*Note: For patients with core needle biopsy only, select the planned surgery type (Lumpectomy or Mastectomy).*

SPECIMEN/PATHOLOGY LOCATION INFORMATION **Indicates a required field. Include a copy of the pathology report.*

*Laterality (Submitted Specimen) ☐ Left ☐ Right	*Tumor Size (mm)	*Specimen ID	*Collection Date (DD/MM/YYYY)
*Pathology Services/Specimen Storage Location		*Address/Suite	
*City	*Country	*Postal Code	*Phone (include country code)	*Fax (include country code)

SPECIAL INSTRUCTIONS/ADDITIONAL CC PHYSICIAN CONTACT INFORMATION *Optional*

Special Instructions		
Additional Physician Name to be Copied on the Final Report	Facility Name	Additional Physician Email

BILLING INFORMATION

☐ **Self-pay:** Payment is required before testing starts. Caris Customer Support 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-Authorization / Authorization #: _____ *(if available)*

☐ **Hospitals/Clinics:** Institution will be billed after testing has been performed.

☐ **Other**, please specify: _____

PHYSICIAN ATTESTATION OF MEDICAL NECESSITY **Indicates a required field.*

This requisition constitutes an order for Caris MI Clarity™ laboratory 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 de-identified 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.

***Authorized Provider Signature**

***Provider Name** (Print)

***Date** (DD/MM/YYYY)

FINAL REPORT WILL BE DELIVERED IN ENGLISH. PLEASE SEE THE REVERSE FOR OPTIMAL SPECIMEN REQUIREMENTS. TERMS AND CONDITIONS APPLY.

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SPECIMEN REQUIREMENTS

FFPE Block	One (1) tumor-containing formalin fixed paraffin embedded block (FFPE) from **most recent lumpectomy, mastectomy or core needle biopsy. Eligible specimen must contain invasive tumor and tissue area ≥4mm²**.
Unstained Slides	Three (3) unstained, positively charged, unbaked slides from one single, tumor-containing formalin fixed paraffin embedded block; 4 micron thickness. Note: A section containing invasive tumor and **tissue area ≥4mm²** is required for Caris MI Clarity™. This test has been validated using the following slides. If submitting slides, please select one: ☐ Avantor VWR Superfrost Plus, Ref# 48311-703 ☐ Epredia Colorfrost Plus Slide, Ref# 9991002 ☐ Epredia Superfrost Plus Gold, Ref# FT4981IGLPLUS-001 ☐ Fisherbrand Superfrost Plus, Ref#1255015 ☐ Matsunami APS, Ref#SUAPS19 ☐ Matsunami CREST, Ref# NTOM1190 ☐ Statlab KT Premium, Ref# KT5+WH-90 ☐ Other: _____ Submission on other slide types will be accepted and tested; however, the likelihood of success may be reduced.

IMPORTANT TREATMENT NOTE

The results for Caris MI Clarity™ will be provided in a report showcasing prognostic classifications of early and late distant recurrence risk based on applicable guidelines (e.g. NCCN, ASCO, ESMO, etc.) in breast cancer for patients who meet the test's intended use criteria. MI Clarity results are intended to be interpreted by a qualified healthcare professional as an adjunct to, and not a substitute for, standard clinicopathologic evaluation. Patient management decisions should not be based solely on MI Clarity results and should be based on the physician's independent medical judgment, taking into consideration all relevant patient information, such as family history, physical examination, results of other diagnostic tests, and patient preferences, and in accordance with the applicable standard of care. 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.

4610 South 44th Place / Phoenix, Arizona 85040 United States of America / (888) 979-8669 / Fax: (866) 479-4925 / CLIA 03D1019490 / CAP 7195577 / ISO 13485:2016 / ISO 15189:2022
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