Caris MI Clarity™ Test Request Form

For Project ID Use Only

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

Please complete and return by fax or email. Incomplete or missing information may result in delayed testing.

ORDERING PHYSICIAN INFORMATION *Section required.*

Name		NPI
Physician Email	Office Contact Name	
Office/Hospital Name	Address	
City	State	Zip
Phone	Fax	

PATIENT INFORMATION *Section required.*

Last Name	First Name			MI
In-Office Medical Record Number	DOB	Age	Biological Sex ☐ M ☑ F	Ethnicity
Address				Apt.
City			State	Zip
Mobile Phone	Email			

TEST DESCRIPTION *Selection required.*

☐ **Caris MI Clarity™**

Caris MI Clarity™ is a risk recurrence profiling tool designed to prognosticate long-term outcomes in early-stage breast cancer. The assay analyzes digitalized Hematoxylin and Eosin (H&E) whole slide images (WSIs) together with clinical inputs to generate probabilities of early distant recurrence (0–5 years) and late distant recurrence (5–15 years). These probabilities are subsequently stratified into categorical risk groups (e.g., low vs. high risk).

Caris MI Clarity™ Patient Eligibility Requirements:

- Breast cancer diagnosis and medically eligible for extended adjuvant therapy
- TNM Stage: T1, T2 or T3 and N0, M0
- Postmenopausal, HR+, HER2-

Ineligible Patients: Premenopausal, HR-, and Node Positive patients are ineligible for this test.

SPECIAL INSTRUCTIONS/ADDITIONAL CC PHYSICIAN CONTACT INFORMATION (OPTIONAL)

Special Instructions		
Additional Physician Name to be Copied	Facility Name	Additional Physician Email

CLINICAL INFORMATION *Section required.*

ICD-10 Code(s)	Primary Tumor/Specimen Site ☑ Breast	TNM Stage ☐ T1 ☐ T2 ☐ T3 ☑ N0 ☑ M0
ER Status ☐ Positive ☐ Negative	PR Status ☐ Positive ☐ Negative	HER2 Status ☐ Positive – Ineligible ☑ Negative
Menopausal Status ☐ Premenopausal – Ineligible ☑ Postmenopausal	Tumor Grade ☐ Low ☐ Medium ☐ High	Surgery Type ☐ Lumpectomy ☐ Mastectomy

SPECIMEN/PATHOLOGY LOCATION INFORMATION *Section required.*

Laterality ☐ Right ☐ Left	Tumor Size (mm)	Specimen ID	Collection Date
Pathology Services/Specimen Storage Location		Address/Suite	
City	State / Zip	Phone	Fax

SPECIMEN REQUIREMENTS

FFPE Block	One (1) tumor-containing formalin fixed paraffin embedded block (FFPE) from most recent lumpectomy or mastectomy. ≥10mm² with ≥ 20% tumor content.
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 with ≥10mm² with ≥ 20% tumor content 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.

BILLING INFORMATION *Attach the front and back of PRIMARY and SECONDARY insurance cards. Patient insurance/payment is REQUIRED to begin testing.*

☐ Insurance ☐ Self Pay

☐ Direct/Client Bill # _____

☐ HMO/Referral # _____

☐ Other _____

Insurance Provider	Policy #	Group #	Insured Name	Insured DOB	Relationship to Patient	Prior Authorization #
Primary						
Secondary						

PHYSICIAN ATTESTATION OF MEDICAL NECESSITY *Signature required.*

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.

Authorized Provider Signature

Provider Name (Print)

Date