AGENDIA
MAMMAPRINT · BLUEPRINT

Test Requisition Form

Fax: 844.711.9132

Clinical Study:

Place Specimen Label Here From Kit Box

*Required Information

SUBMISSION STATUS

☐ First Submission ☐ Resubmission ☐ Associated Order Number _____

CLINICAL INFORMATION AT TIME OF ORDER

NODAL STATUS*
- ☐ (NX) Not Submitted or Found
- ☐ (N0) Negative
- ☐ (N1) 1-3 Nodes
- ☐ (N2 or N3) ≥ Greater than or equal to 4 Nodes
- ☐ Clinical Assessment

TUMOR INFORMATION*

Tumor Size (check one):
- ☐ ≤ Less than or equal to 5.0 cm
- ☐ > Greater than 5.0 cm

Tumor Grade: ☐ 1 ☐ 2 ☐ 3

☐ Clinical Assessment

HORMONE RECEPTOR STATUS*

	Positive	Negative	Equivocal
ER	☐	☐	
PR	☐	☐	
HER2	☐	☐	☐

REQUESTED TESTS:

☐ Perform test(s) per Standing Order on file ☐ MammaPrint & BluePrint ☐ MammaPrint Only (70 Gene Breast Cancer Recurrence Assay) ☐ BluePrint Only (80 Gene Molecular Subtyping Assay)

CLIENT INFORMATION*

Account Name

Account Address

Account City | Account State | Account Zip Code

Account Phone | Account Fax

ORDERING PHYSICIAN INFORMATION & SIGNATURE

As the physician of record, I have concluded that the test(s) I am ordering is medically necessary for treatment of this patient. I anticipate that this test(s) will provide prognostic and/or predictive information which has not been obtained already. I confirm the patient consented for this test to be performed for this purpose. This Order form is part of the medical record, is consistent with other entries in the record, and accurately describes the reason(s) I am ordering the tests.
If indicated on the Test Request Form that I am ordering the test(s) as part of an authorized clinical trial, I confirm that the patient consented in writing to participate in the clinical trial, and that my ordering of the test(s) for this patient is consistent with the applicable clinical trial protocol.
I also confirm that to the extent necessary, and consistent with any applicable clinical trial protocol, the patient consented for Agendia, Inc. to release test information when necessary to obtain reimbursement. In submitting this Order, I acknowledge that I have read and agree to be bound by Agendia's General Terms of Service found here: https://agendia.com/terms-conditions/general-terms-of-service/.

Ordering Physician Name* | Created By

Ordering Physician Signature* | Date* | Ordering Physician Phone

Ordering Physician NPI | Ordering Physician Fax | Additional Report Recipient Email/Fax

PATIENT INFORMATION*

Patient Name: Last, First, Middle

Address

City | State | Zip | Country

Date of Birth (MM/DD/YYYY) | Patient Phone

Gender: ☐ Female ☐ Male

MRN: _____

Hospital Status ☐ Hospital Inpatient (>24hr Stay) ☐ Hospital Outpatient ☐ Non Hospital Patient

Date of Hospital Discharge: _____

BILLING INFORMATION

COMPLETE the following & attach copy of face sheet and front and back of insurance card

Billing Type: ☐ Private Insurance ☐ Medicare ☐ Patient ☐ Bill Client (Restricted to contracted accounts on file at Agendia)

Submitting Diagnosis*

i.e. C50.21

ICD-10 Code*

Primary Insurance Name* | Member ID*

Prior Auth # (if available) | Phone*

Secondary (if applicable)* | Member ID*

Relationship to insured: ☐ Self (skip section) ☐ Spouse ☐ Dependent

Other: Insured DOB* MM/DD/YYYY

PATHOLOGY INFORMATION*

☐ Agendia to request specimen from pathology ☐ Ordering physician to request specimen from pathology

Facility

Address

City | State | Zip | Country

Phone | Fax | Email

Collection Date*

If multiple primaries: ☐ Agendia to choose best block ☐ Test all blocks

Additional Comments

PLEASE INCLUDE PATHOLOGY AND IMAGING REPORTS WITH TEST REQUEST

Specimen ID*	Specimen Type*	Specimen Site*	Container Type*	Qty*
1.	☐ Core Biopsy ☐ Surgical ☐ Other	☐ Left Breast ☐ Right Breast ☐ Other _____	☐ Block ☐ Slides	
2.	☐ Core Biopsy ☐ Surgical ☐ Other	☐ Left Breast ☐ Right Breast ☐ Other _____	☐ Block ☐ Slides	
3.	☐ Core Biopsy ☐ Surgical ☐ Other	☐ Left Breast ☐ Right Breast ☐ Other _____	☐ Block ☐ Slides	

TERMS AND CONDITIONS
AGENDIA, INC. CLINICAL LABORATORY TESTING REQUISITION

INTENDED USE(S)

MammaPrint® FFPE is a qualitative in vitro diagnostic test, performed in a central laboratory, using the gene expression profile obtained from formalin-fixed paraffin embedded (FFPE) breast cancer tissue samples to assess a patient's risk for distant metastasis within 5 years.

MammaPrint FFPE is performed for breast cancer patients, with Stage I or Stage II disease, with tumor size ≤ 5.0 cm and lymph node negative. The MammaPrint FFPE result is indicated for use by physicians as a prognostic marker only, along with other clinico-pathological factors.

SPECIAL CONDITIONS FOR USE STATEMENT(S)

MammaPrint FFPE and BluePrint® FFPE are not indicated as a standalone test to determine the outcome of disease, nor to suggest or infer an individual patient's likely response to therapy. Results should be taken in the context of other relevant clinico-pathological factors and standard practice of medicine.

MammaPrint FFPE and BluePrint FFPE are for prescription use only.

PHYSICIAN AUTHORIZATION

MammaPrint FFPE and BluePrint FFPE must be ordered by a physician or other qualified healthcare professional who has concluded that the test is medically necessary for the treatment of the patient and will provide prognostic and/or predictive information which has not been obtained already.

If any test is ordered as part of an authorized clinical trial, the order must be consistent with the applicable clinical trial protocol.

SPECIMEN HANDLING AND SERVICE STANDARDS

Agendia will provide laboratory diagnostic testing upon the receipt of a valid physician (or qualified healthcare professional) order that includes the information necessary for Agendia to bill the patient or responsible third party, to the extent applicable, for the services provided.

Agendia shall handle and process the specimen(s) and perform the ordered laboratory testing professionally and to the best of its abilities in accordance with industry standards and applicable CLIA regulations. However, the client acknowledges that Agendia cannot and will not guarantee that the services will always be error-free. Agendia specifically disclaims any and all representations and warranties regarding its products and services, to the extent permitted by law, other than those expressly made in writing by Agendia, including the warranty literature for the product or service (if any). This disclaimer includes but is not limited to any representations or warranties as to the quality, reliability, fitness for purpose or any other feature of the products and/or services.

CLIENT RESPONSIBILITIES

The client will provide Agendia with all data and other information required and necessary for Agendia to deliver the laboratory services.

The client warrants that the information provided to Agendia is correct and complete, and that it is entitled to provide Agendia with such information for the delivery of the laboratory services.

If any of the data provided is personal data or data otherwise protected by law, the client guarantees that with regard to such data, any and all applicable regulations and other legal requirements for the protection of privacy have been met and that Agendia is entitled to use and process such personal data.

The client shall give and make no warranty or representation on behalf of Agendia's products and/or services as to quality, reliability, fitness for purpose or any other feature of the products and/or services other than as explicitly set forth in writing by Agendia in the applicable warranty literature.

The client shall be solely liable for any claims arising out of or relating to the improper or faulty collection and/or handling of any specimen(s), any errors in transmission of information or data to Agendia, or any illegal or tortious act committed by the client, or his or her representatives, staff, affiliates, or associates or its employees, agents or assigns.

MEDICARE COVERAGE CRITERIA

MammaPrint FFPE is a diagnostic test that analyzes the gene expression profile of FFPE breast cancer tissue samples to assess a patient's risk for distant metastasis. MammaPrint was prospectively validated as a microarray assay in the 6,693 patient MINDACT trial in early stage breast cancer, tumor size ≤ 5.0 cm, up to 3 positive lymph nodes and independent of receptor status.

By ordering MammaPrint FFPE, the client has determined that the patient meets the applicable coverage criteria, however, if the client believes the coverage criteria is not met, the client should also provide to Agendia with an advance beneficiary notice (ABN) signed by the patient, in accordance with Medicare standards.

FEES AND BILLING

Agendia shall bill patients and/or third-party payors (e.g., private insurance, Medicare, etc.) in accordance with applicable policies and regulations for all laboratory services performed. Clients shall not bill any third party for any service performed by Agendia unless under contractual agreement, or in accordance with applicable policies.

The client agrees that a legally binding agreement that includes Agendia, Inc.'s General Terms of Service (available here: https://agendia.com/terms-conditions/general-terms-of-service/ and these clinical laboratory testing requisition terms and conditions shall arise as soon as Agendia accepts the test order by email, written confirmation or the moment Agendia starts executing such an order, whichever occurs first.