Clinical Study:

Place Specimen Label Here From Kit Box

Test Request Form

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AGENDIA
PRECISION ONCOLOGY

ORDERING PHYSICIAN TO COMPLETE

SECTION 1. SUBMISSION STATUS

☐ First Submission ☐ Resubmission ☐ Agendia to request specimen from pathology ☐ Ordering Physician to request specimen from Pathology

SECTION 2. CLIENT INFORMATION

Account Details:

Ordering Physician (Select One)

NPI

SECTION 3. PHYSICIAN SIGNATURE

I represent that I am treating this patient as the physician of record and authorizing the performance of the test(s) identified on this Order. I have concluded that the test(s) I am ordering is medically necessary for treatment of this patient because I anticipate that this test(s) will provide prognostic and/or predictive information which has not been obtained already. 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 test(s). In submitting this Order, I acknowledge I have read and agree to be bound by Agendia's General Terms & Conditions.

Apologies

Print Name

Signature of Ordering Physician (See General Terms and Conditions) Date

SECTION 4. PATIENT INFORMATION

Patient Name: Last, First, Middle

Address

City St Zip Country

MM/DD/YYYY
Date of Birth Patient Phone

Gender: ☐ Female ☐ Male

MRN:

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

Date of Hospital Discharge:

SECTION 5. 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 Insurance Name Member ID

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

Other: Insured DOB MM/DD/YYYY Insured SSN

SECTION 6. SPECIMEN INFORMATION

Collection Date MM/DD/YYYY **Specimen Type** ☐ FFPE Block ☐ FFPE Slides ☐ Right Breast ☐ Left Breast ***Please include pathology report with test request***

Nodal Status (Check one)
☐ Lymph Node-Negative (N0)
☐ Lymph Node Status Unknown (NX)

Node Positive
Number of Positive Nodes (N1 or N1mi)
Tumor Grade (Nottingham or Elston) - Check one:
☐ 1 ☐ 2 ☐ 3 If mixed grade, select higher grade for classification

Hormone Receptor
Status: ☐ ER+ ☐ ER- ☐ PR+ ☐ PR-
HER2 Status: ☐ HER2- ☐ HER2+
Tumor Size: _____ . _____ cm

SECTION 7. TEST MENU

☐ **Agendia Breast Cancer Test Suite (includes MammaPrint® and BluePrint®)**

☐ MammaPrint, **70-Gene Breast Cancer Recurrence Assay**

☐ BluePrint, **80-Gene Molecular Subtyping Assay**

SECTION 8. STANDING ORDERS

***See next page for Medicare Coverage Criteria**

Agendia will perform any test(s) indicated by standing orders on file from the ordering physician unless otherwise requested: ☐ Perform test(s) marked on requisition only

SECTION 9. PATHOLOGY INFORMATION (SLIDE OR BLOCK SPECIMENS)

Facility

Address

City St Zip Country

Phone Fax Email

Specimen ID:

1: 2:

3: 4:

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

Additional Comments

Lab use only

AGENDIA GENERAL TERMS AND CONDITIONS

A. Agendia shall perform the ordered laboratory testing professionally and to the best of its abilities. However, the client acknowledge that Agendia can not 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.

B. The client agrees that a legally binding agreement that includes these General Conditions shall arise as soon as Agendia accepts the physician's order by e-mail or written confirmation or on the moment Agendia starts executing such order. The client's placement of such an order or other manifestation of assent Agendia constitutes express acceptance of these General Conditions.

C. The client will at all times timely and completely provide Agendia with all data and other information required by Agendia and necessary for the delivery of the products and/or services.

D. The client warrants that the information provided pursuant to Agendia is correct and complete, and that it is entitled to provide Agendia with such information for the delivery of the products and/or services. The client shall indemnify, defend, and hold harmless Agendia against all claims by a third party or governmental entity, relating to or arising out of the provision of such information to Agendia, and shall pay any costs incurred by Agendia relating thereto, including but not limited to attorney's fees, defense costs, and any award of damages.

E. 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 personal such data. The client shall indemnify, defend, and hold harmless Agendia against any third party's claims relating to or arising out of any claim by a third party or governmental entity that appropriate privacy protections or legal requirements were not met and shall pay any costs incurred by Agendia relating thereto, including but not limited to attorney's fees, defense costs, and any award of damages. If and to the extent that the client provides Agendia with its own private, personal, sensitive, or protected data, the client herewith explicitly authorized Agendia to keep and to process such data as reasonably necessary to fulfill Agendia's obligation under the agreement or other legal act existing between the Parties. Agendia will take all reasonable steps necessary to comply with any and all applicable privacy regulations and laws.

F. 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 warranty literature applicable to the specific Product and/or Service (if any). If the client, or his or her representatives, staff, affiliates, or associates alters or expands any existing warranty or extends any additional warranty, expressly or impliedly, the client shall indemnify, defend, and hold harmless Agendia for any and all claims by a third party or governmental entity relating to such additional warranty and shall pay any costs incurred by Agendia relating thereto, including but not limited to attorney's fees, defense costs, and any award of damages.

G. 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 sample(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. The client shall indemnify, defend, and hold harmless Agendia for any such claims by a third party or governmental entity and shall pay any costs incurred by Agendia relating thereto, including but not limited to attorney's fees, defense costs, and any award of damages.

H. The client, and his or her representatives, staff, affiliates, and associates undertake to observe strict confidentiality with regard to all confidential information it receives from Agendia. It shall impose the aforementioned obligation on its employees as well as to third parties who have been employed by them in connection with the agreement between the parties. The client, his or her representatives, staff affiliates, and associates shall use the confidential information only for the purpose for which it has been provided.

I. Regardless of the nature of such information, the client agrees to take any and all reasonable measures to keep any information confidential if Agendia indicates such information to be confidential.

J. Agendia shall not be liable for any loss or damages, either direct or consequential, such as loss of business, profits, good will or similar, incurred by the client or by any third party, including any legal liability or damages. If Agendia is deemed liable despite this provision, any damages to be paid by Agendia to the client with respect to products or services provided under the agreement will, in any case, be limited to compensation of the direct damages and/or loss not to exceed the sum paid for the products or services provided under the order at issue. Agendia shall not be liable for any loss, damage or delay during shipping. Under no circumstances will any liability exceed the amount which is paid out in the matter concerned under the professional liability policy entered into by Agendia, to be increased by the amount of the deductible which according to the terms and conditions of the insurance policy will not be for the account of the insurer.

MEDICARE COVERAGE CRITERIA

MammaPrint was prospectively validated in the 6,693 patient MINDACT trial in early stage breast cancer, <5cm up to 3 positive lymph nodes and independent of receptor status.

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.

The test 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)

For prescription use only.

MammaPrint FFPE is 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.