MammaPrint® and BluePrint® Summary

Patient Name: Last, First

Age: 75 **DOB:** 01-Jan-1950 **Specimen ID:** SID-124856789XX **MRN:** MRN-123456789XX

AGENDIA MAMMAPRINT+BLUEPRINT

CLINICAL INFORMATION

Receptor Status: ER+ / PR+ / HER2-

Tumor Grade: 1

Specimen Type: FFPE, Needle Core

Nodal Status: Positive

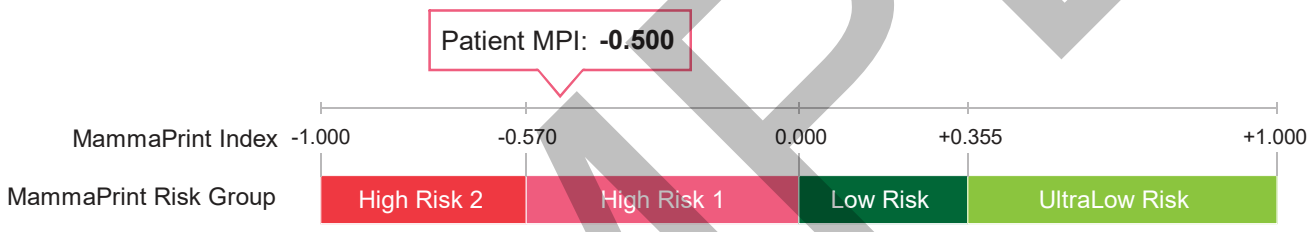
Tumor Size: 2.8 cm

Age: >50 years

Clinical characteristics were determined using information that was provided at the time of test request from:
Test Pathology Lab, 999 Broadway Ave, Irvine, CA 92618

GENOMIC TESTING RESULTS

MammaPrint Risk Group	MammaPrint Index	BluePrint Molecular Subtype
High Risk 1	**-0.500**	**Luminal B**



CLINICAL IMPLICATIONS

Neoadjuvant Chemotherapy Planning

Probability of pCR with Neoadjuvant Chemotherapy

6%

NBRST[A]

Adjuvant Chemotherapy Planning

Expected Chemotherapy Benefit

Yes

MINDACT[D]

5-Year Distant Risk of Recurrence High Risk 1

With ET alone	With ET & CT
10% (6%-15%)*	**4%** (3%-6%)*

Absolute Chemotherapy Benefit

6% (3%-8%)*

FLEX[B]

*Indicates lower and upper bound observed within the MammaPrint Risk Group

Adjuvant Endocrine Therapy Planning

Standard Endocrine Therapy Benefit

Yes

STO-3[C]

Absolute Benefit from Extended Endocrine Therapy

No

NSABP B-42[E]

CT: Chemotherapy
ET: Endocrine Therapy (TAM or AI)
MPI: MammaPrint Index
pCR: Pathologic Complete Response

SAMPLE

Note: This summary is provided for general informational purposes. It is not part of any official diagnostic report. Please refer to individual MammaPrint and BluePrint reports for comments, assay information, and references. Expected chemotherapy benefit is based on administration of therapy within standard guidelines and timeframe.

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22 Morgan, Irvine, CA 92618 | Phone: 888.321.2732 | Fax: 844.711.9132 | customercare@agendia.com | www.agendia.com
Radarweg 60, 1043 NT Amsterdam, the Netherlands | Phone: +31.(0)20.462.1510 | customerservice@agendia.com | www.agendia.com

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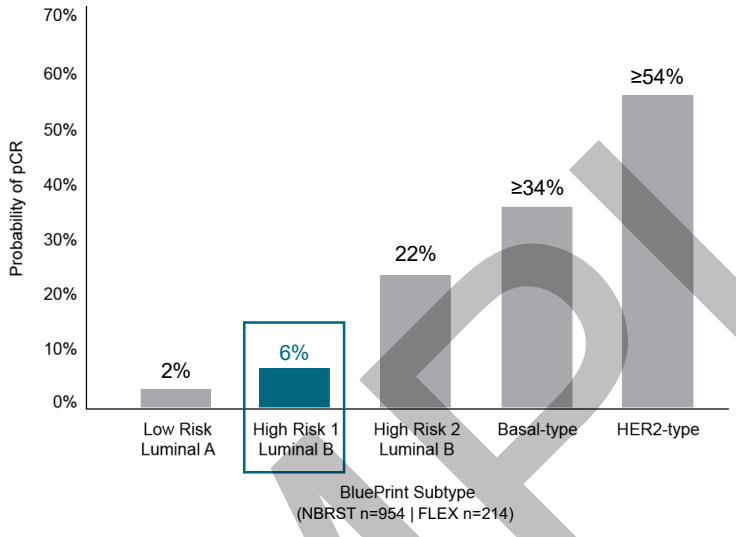
NEOADJUVANT CHEMOTHERAPY PLANNING DATA*

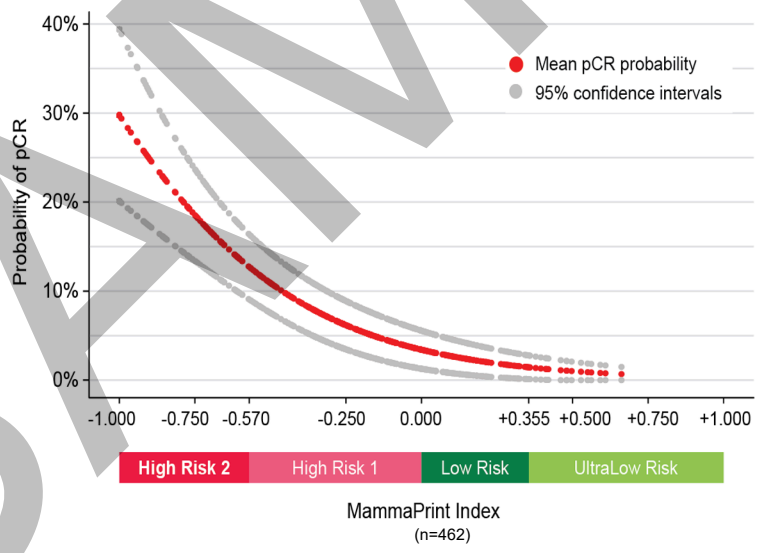
Probability of pCR Based on BluePrint Subtype and MP Risk Group

NBRST/FLEX[A,B]



Probability of pCR Based on MPI and MP Risk Group

NBRST[A]



*** Clinical implications are based on observed outcomes from clinical research studies depicted above and further referenced on page 4. Results should be taken in the context of all other relevant clinico-pathological factors and standard practice of medicine.**

MP: MammaPrint | **MPI:** MammaPrint Index | **pCR:** Pathologic Complete Response

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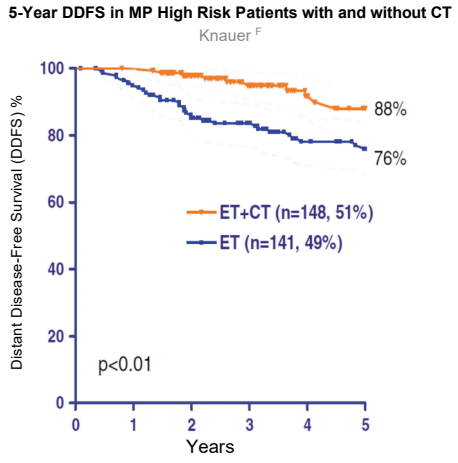
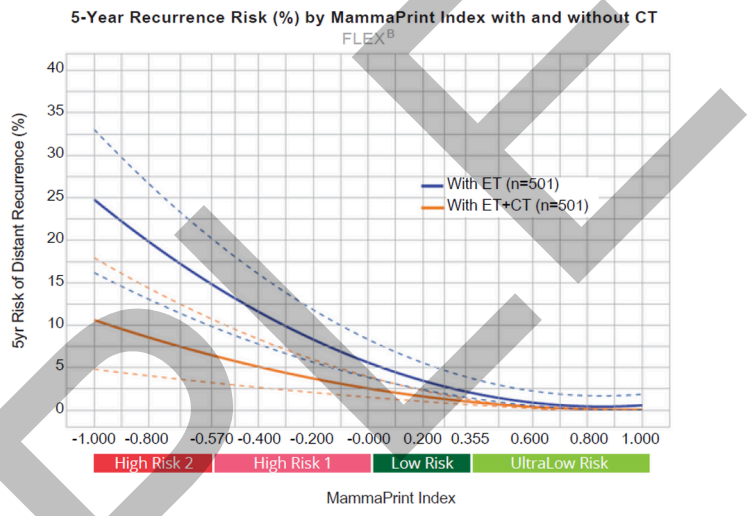
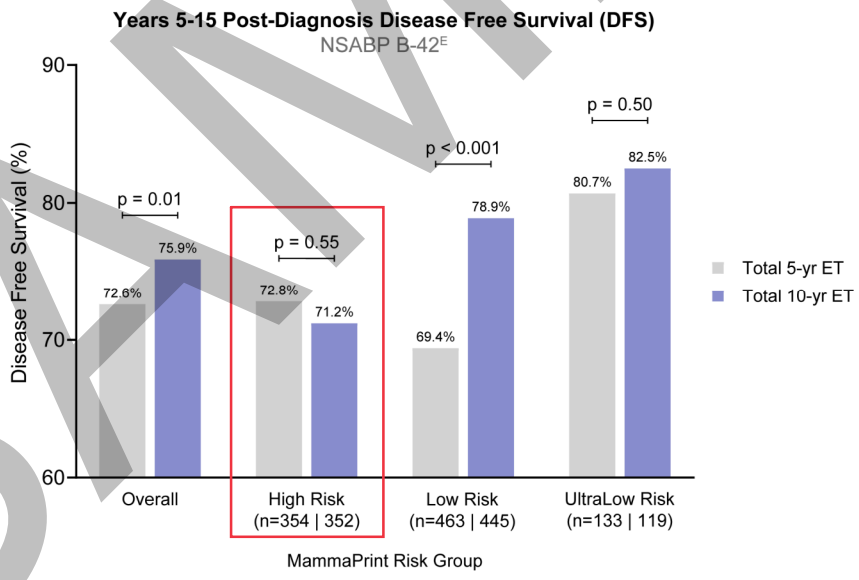
ADJUVANT CHEMOTHERAPY PLANNING DATA*



Predicted benefit of chemotherapy included both clinically high risk and clinically low risk patients at 5 years



ADJUVANT ENDOCRINE THERAPY PLANNING DATA*



***Clinical implications are based on observed outcomes from clinical research studies depicted above and further referenced on page 4. Data supporting adjuvant endocrine therapy planning were generated from studies composed of predominantly HR+, post-menopausal women (>50 years old). Menopausal status at 5 years post-diagnosis can be used to determine the application of data for adjuvant endocrine therapy planning. Results should be taken in the context of all other relevant clinico-pathological factors and standard practice of medicine.**

CT: Chemotherapy | **DFS:** Disease-Free Survival | **ET:** Endocrine Therapy | **MP:** MammaPrint

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AGENDIA
MAMMAPRINT+BLUEPRINT

PATIENT AND ORDERING INFORMATION

PATIENT

Patient Name:	Last, First
Date of Birth:	01-Jan-1950
Age:	75
MRN:	MRN-123456789XX
Sex:	Female

PHYSICIAN

Ordering Physician:	Doe, Jane
Customer Reference #:	CREFXXXXXX
Account:	ABC Oncology
Address:	123 ABC Oncology Way
	City, State 12345

SPECIMEN

Specimen ID:	SID-124856789XX
Specimen Type:	FFPE, Needle Core
Specimen Source:	Right Breast
Collection Date:	15-Dec-2024
Performed Date:	20-Dec-2024
Reported Date:	08-Jan-2025

CLINICAL STUDY AND TRIAL REFERENCES

A. NBRST: A prospective study that included 1,069 patients with histologically proven early stage breast cancer (ESBC), aged 18–90 years, who were scheduled to receive neoadjuvant therapy. Patients were enrolled from 40 US institutions and received both MammaPrint and BluePrint genomic testing. Treatment was at the discretion of the physician adhering to NCCN-approved or other peer-reviewed, established regimens. Intrinsic preoperative chemosensitivity and long-term outcomes were precisely determined by MammaPrint and BluePrint regardless of patient age, supporting the utility of these assays to inform treatment and surgical decisions in ESBC.[1-4]

B. FLEX (NCT03053193): An ongoing prospective, observational trial that has enrolled >17,000 patients with ESBC who were tested with MammaPrint as standard of care, with or without BluePrint, and consented to clinically annotated full transcriptome data collection (data locked August 2024).[5-7]

C. STO-3: The Stockholm tamoxifen trial included 1,780 lymph node-negative, hormone receptor-positive, post-menopausal patients with tumors smaller than or equal to 3 cm in diameter, randomized to 2 (65%) to 5 (35%) years of adjuvant tamoxifen vs no adjuvant treatment. MammaPrint was retrospectively assessed on a translational cohort of 652 patients; 313 had received tamoxifen (2–5 years) and 339 had not received adjuvant systemic therapy.[8,9]

D. MINDACT: A phase 3, prospective, randomized clinical trial that enrolled 6,693 patients at 112 academic and community hospitals in 9 European countries. Patients were eligible to enroll if they were women aged 18–70 years with histologically confirmed unilateral primary non-metastatic (M0) invasive breast cancer (clinical stage T1 or T2 or operable T3) with 0–3 positive axillary lymph nodes. For hormone-positive women ≤ 50 years, there was a 2.6% benefit in 5-year distant metastasis free survival for women who received chemotherapy (CT) vs those that received endocrine therapy (ET) alone. Although this difference is possibly due to CT-induced ovarian function suppression, it should be part of informed, shared decision making.[10,11]

E. NSABP B-42: An adjuvant extended endocrine therapy (EET) trial which included 3,966 post-menopausal women with stage I–IIIA hormone receptor-positive breast cancer, who were disease-free after 5 years of ET. Patients were randomized to receive either an additional 5 years of letrozole (EET) or placebo. MammaPrint was retrospectively analyzed on a translational cohort of 1,866 patients; 916 patients received EET and 950 patients received placebo.[12]

F. Knauer: A retrospective study that included 541 patients with stage pT1–3, N0–1 invasive breast cancer with known adjuvant treatment status. 252 (47%) and 289 (53%) were classified as MammaPrint Low Risk and High Risk, respectively. A 12% absolute reduction in recurrence risk (50% relative risk reduction) was observed in 5-year distant disease-free survival among MammaPrint High Risk patients who were treated with ET and CT versus those who were treated with ET alone, which was statistically significant.[13]

References:

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10. Piccart M et al. Lancet Oncol. 2021;22(4):476-488.
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12. Rastogi P et al. J Clin Oncol. 2024;00:1-9.
13. Knauer M et al. Breast Cancer Res Treat. 2010;120(3):655-61.

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CE 0459 IVD
Agendia NV
Radarweg 60
1043 NT Amsterdam, the Netherlands

Agendia, Inc.
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