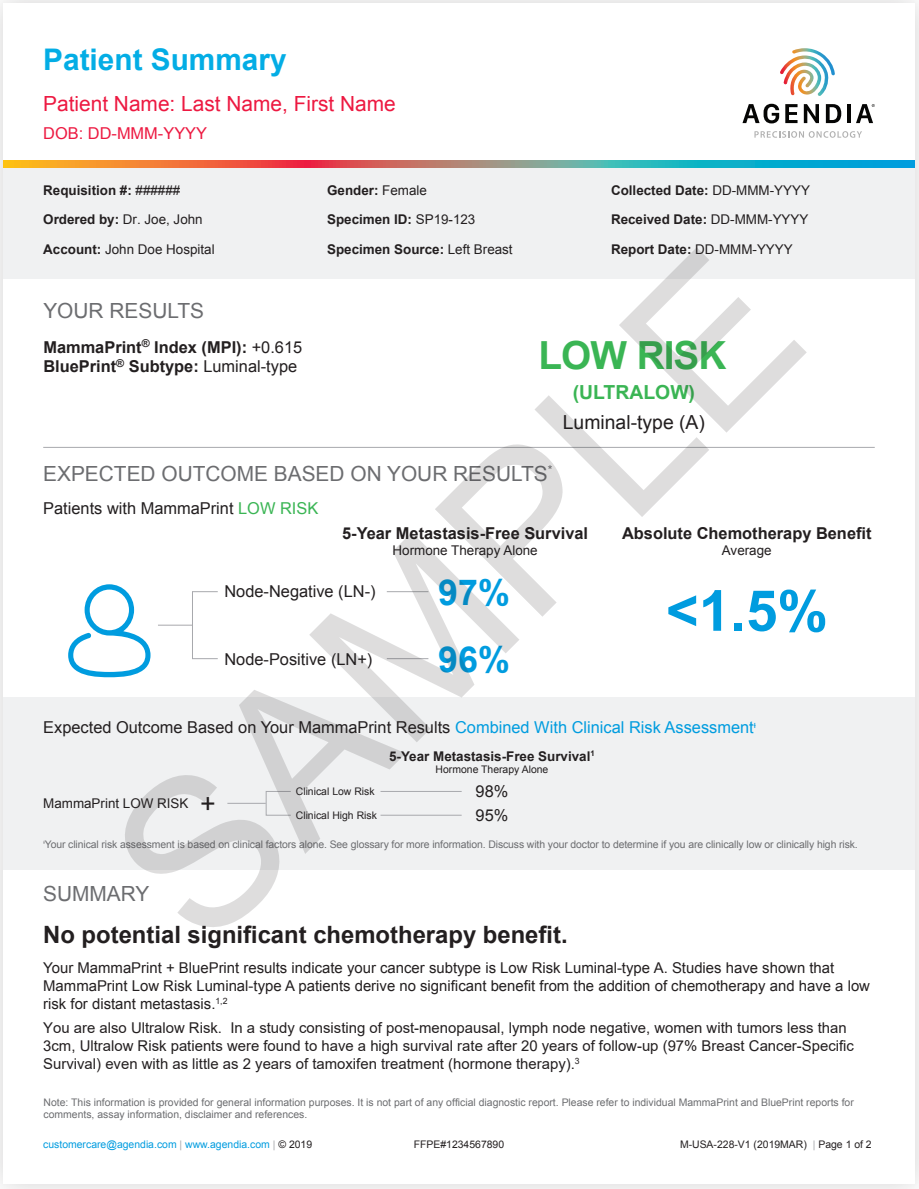
# Agendia® Patient Summary Overview

ULTRALOW RISK

A new resource for patients and an aid for physician-patient discussions and shared decision-making

FRONT



## Patient Summary

Patient Name: Last Name, First Name
DOB: DD-MMM-YYYY

AGENDIA
PRECISION ONCOLOGY

**Requisition #:** ######
**Ordered by:** Dr. Joe, John
**Account:** John Doe Hospital

**Gender:** Female
**Specimen ID:** SP19-123
**Specimen Source:** Left Breast

**Collected Date:** DD-MMM-YYYY
**Received Date:** DD-MMM-YYYY
**Report Date:** DD-MMM-YYYY

YOUR RESULTS

**MammaPrint® Index (MPI):** +0.615
**BluePrint® Subtype:** Luminal-type

**LOW RISK**
**(ULTRALOW)**
Luminal-type (A)

SAMPLE

EXPECTED OUTCOME BASED ON YOUR RESULTS*

Patients with MammaPrint LOW RISK

| | 5-Year Metastasis-Free Survival (Hormone Therapy Alone) | Absolute Chemotherapy Benefit (Average) |
|---|---|---|
| Node-Negative (LN-) | 97% | <1.5% |
| Node-Positive (LN+) | 96% | |

Expected Outcome Based on Your MammaPrint Results Combined With Clinical Risk Assessment†

| | | 5-Year Metastasis-Free Survival[1] (Hormone Therapy Alone) |
|---|---|---|
| MammaPrint LOW RISK + | Clinical Low Risk | 98% |
| | Clinical High Risk | 95% |

†Your clinical risk assessment is based on clinical factors alone. See glossary for more information. Discuss with your doctor to determine if you are clinically low or clinically high risk.

SUMMARY

**No potential significant chemotherapy benefit.**

Your MammaPrint + BluePrint results indicate your cancer subtype is Low Risk Luminal-type A. Studies have shown that MammaPrint Low Risk Luminal-type A patients derive no significant benefit from the addition of chemotherapy and have a low risk for distant metastasis.[1,2]

You are also Ultralow Risk. In a study consisting of post-menopausal, lymph node negative, women with tumors less than 3cm, Ultralow Risk patients were found to have a high survival rate after 20 years of follow-up (97% Breast Cancer-Specific Survival) even with as little as 2 years of tamoxifen treatment (hormone therapy).[3]

Note: This information is provided for general information purposes. It is not part of any official diagnostic report. Please refer to individual MammaPrint and BluePrint reports for comments, assay information, disclaimer and references.

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The patient's individualized results
- MammaPrint® Index
- BluePrint® subtype
- If a patient has a MPI >+0.355, they are classified as having ULTRALOW risk

From the MINDACT trial, expected prognosis and benefit of treatment information provided for both LN-and LN+ patients

- MammaPrint LOW Risk patients had less than a 1.5% non-statistically significant difference between CT and No CT at 5 years

Combined clinical and genomic risk information provided to help further refine risk prognosis

Simplified summary statement for patients which helps to easily interpret what impact the results may have on potential treatment decisions

- For ULTRALOW risk patients, additional 20-year follow-up outcome results provided, as observed from an analysis of the STO-3 trial

AGENDIA®
MAMMAPRINT+BLUEPRINT

# Agendia® Patient Summary Overview

ULTRALOW RISK

## Interpreting the new MammaPrint® and BluePrint® patient summary

REVERSE

### Patient Summary

AGENDIA
PRECISION ONCOLOGY

#### *EXPECTED OUTCOMES BASED ON YOUR RESULTS

**5-Year Metastasis-Free Survival:** This is the percentage of patients whose cancer did not spread from the original tumor to distant sites after 5 years when treated with hormone therapy alone. Node-negative results were observed in ER+, LN- patients in the MINDACT trial; node-positive results were observed in clinically high risk, ER +/-, LN+ patients in the MINDACT trial.[1]

**Absolute Chemotherapy Benefit (average):** A difference of 1.5% was observed between clinically high risk patients with MammaPrint Low Risk results who were treated with hormone therapy alone versus those who were treated with hormone therapy and chemotherapy in the MINDACT trial.[1] This difference of 1.5% is considered not statistically significant, meaning the results are not definite and could be due to chance.

#### GLOSSARY OF TERMS

**Breast Cancer-Specific Survival (BCSS):** The percentage of people in a study or treatment group who have not died from breast cancer in a defined period of time.

**Cancer/Molecular Subtype:** In breast cancer, most studies divide breast cancer into four major molecular subtypes: Luminal A, Luminal B, Triple-negative/Basal-like, and HER2 type. The BluePrint subtypes are defined by these active biological pathways. Knowing your cancer's subtype can help determine the best course of treatment

- **Luminal-type:** Luminal-type cancers are typically hormone receptor-positive tumors and are likely responsive to hormonal therapy.
- **Basal-type:** Basal-type cancers are typically "triple-negative" for ER, PR and HER2 receptor expression. These tumors typically do not respond to hormone therapy or anti-HER2 targeted therapy. Basal-type cancers tend to grow more rapidly.
- **HER2-type:** HER2-type cancers tend to grow more rapidly and may recur, although they can often be treated with anti-HER2 targeted therapies such as trastuzumab, pertuzumab and lapatinib.

**Chemotherapy:** Chemotherapy can be an effective treatment for properly selected patients. It is called a systemic therapy because the drugs enter the bloodstream and travel throughout the body. It works by killing cells that divide rapidly, like cancer cells. Side effects may include hair loss, nausea, mouth sores, nerve damage, and other problems.

**Clinical Risk:** The estimated risk of recurrence based on clinical factors alone, such as receptor status, tumor size, tumor grade, and lymph node status.

**Hormone Therapy (anti-estrogen):** Treatment typically used with breast cancers that are "estrogen receptor-positive" (ER+) and/or "progesterone receptor-positive" (PR+). Some tumors need estrogen and/or progesterone to keep growing. Hormone therapy either stops your body from making those hormones, or blocks the receptors so the cancer cannot use the hormones for its growth.

**"Low/High Risk" MammaPrint Results:** The MammaPrint test classifies your breast cancer as having either a "Low Risk" or a "High Risk" of recurrence. A MammaPrint "Low Risk" result indicates low likelihood of your cancer recurring, and a "High Risk" result indicates higher likelihood of your cancer returning.

**Metastasis/Distant Metastasis:** The spread of cancer cells from the original (primary) tumor to distant organs or distant lymph nodes. The absence of metastasis in a given time period is also referred to as Distant Metastasis-Free Survival (DMFS).

**Node-Negative (also known as Lymph Node-Negative or LN-):** When lymph nodes are free, or clear, of cancer.

**Node-Positive (also known as Lymph Node-Positive or LN+):** A finding of cancer cells in the lymph nodes.

**Statistically Significant:** A difference in results that is not attributed to chance, or in other words a reliable result.

#### RESOURCES TO LEARN MORE

For other resources, please visit the American Cancer Society at www.cancer.org, our corporate website at Agendia.com, or connect with our patient community through the Symphony Sisterhood Facebook page, or @SymphonySister on Twitter.

#### TREATMENT NOTES


**References:**
1. Cardoso, F., et al. N Engl J Med. 2016 Aug 25;375(8):717-29.
2. Whitworth, P., et al. Ann Surg Oncol. 2014 Oct;21(10):3261-7.
3. Esserman, L.J., et al. JAMA Oncol. 2017 Nov 1;3(11):1503-1510.








Explanation of the expected outcomes as observed in the MINDACT trial: LOW risk patients derive no significant benefit from chemotherapy

Helpful and patient friendly glossary of terms

Dedicated area for patient to take notes on treatment decisions, helpful information or other details

**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.

**BluePrint®** is a laboratory-developed test that was developed, validated and is performed exclusively by Agendia. The test is intended for clinical purposes. The test has not been cleared by the U.S. Food and Drug Administration (FDA) but has been CE-marked for use in Europe. The laboratory is regulated under the Clinical Laboratory Improvement Amendments (CLIA) to ensure the quality and validity of the tests. Our laboratories are CAP-accredited and certified under CLIA to perform high complexity clinical laboratory testing.