



mammaprint®

*decoding breast cancer.*

Learn how the MammaPrint  
breast cancer test can help you and your  
doctor make the right treatment decisions, *just for you.*

## MammaPrint®: Developed by a woman, for women.



Eligio Paoni/ Contrasto

“What really inspired me to bring MammaPrint to the medical community was the true benefit it offers women with breast cancer.

This test provides women and doctors better insight into individual risk and allows for more informed, personalized treatment decisions.”

Laura van 't Veer, Ph.D.

Dr. Laura van 't Veer's pioneering work has been widely acknowledged within the scientific community, earning her the Lifetime Achievement Award for Translational Cancer Research from the European Society of Medical Oncology. She has also received accolades from the public sector including Oprah Winfrey recognizing her work on MammaPrint as one of the “*five biggest health breakthroughs by women scientists*” of all-time.

In a world where researchers and clinicians rarely cross paths, Dr. Laura van 't Veer is both. She has an extensive background in cancer biology and molecular oncology, completing her postdoctoral studies at such prestigious institutions as Harvard Medical School and Massachusetts General Hospital and earning her PhD at the University of Leiden, the Netherlands. After joining the Netherlands Cancer Institute (NKI), Dr. van 't Veer began a dialogue with surgeons, medical oncologists and radiologists to address a pressing medical need: the treatment of early stage breast cancer.

Dr. van 't Veer focused her research on developing a breast cancer gene expression test with which she and other scientists could analyze multiple tumor genes and their relationship with one another. Through rigorous discovery and validation studies, Dr. van 't Veer and an expert team of scientists identified 70 critical genes involved in breast cancer metastasis, which comprise the MammaPrint gene signature, with the intent of predicting the risk of metastatic disease. In the clinical setting, this translated into reducing unnecessary chemotherapy for women at low risk of metastasis, while at the same time helping identify high risk women who may benefit from therapy.

Dr. van 't Veer played a pivotal role in developing one of the key advances in women's healthcare of our time —by a woman and for women throughout the world. Today, she is the Chief of the Diagnostic Oncology Division at The Netherlands Cancer Institute.



## What treatment is right for you?

When you are first diagnosed with breast cancer, your doctor needs to establish if you are at risk for metastasis and your tumor recurring. Based on your individual risk of recurrence, whether or not your cancer has the potential to spread, your doctor will determine the best therapy for you. If you are at low risk for recurrence, hormonal therapy alone may be recommended. Conversely, if you are at high risk, your doctor may recommend more aggressive treatment that may include chemotherapy. This distinction is crucial for determining the best possible treatment plan specifically for you.

Now you and your physician have an FDA-cleared test that can help make this vital determination. MammaPrint provides a “Low Risk” or “High Risk” result for every patient tested. With MammaPrint there is no ambiguity about your individual risk, thereby helping you and your doctor determine your need for therapy.

Ask your doctor how MammaPrint can help you develop a treatment plan tailored precisely for you.

## Questions & Answers

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### What is MammaPrint?

MammaPrint is the only FDA-cleared gene expression profile test validated to assess your individual risk of breast cancer metastasis. Truly, a “next-generation” diagnostic test, MammaPrint leverages the advances made by the Human Genome Project and the newest developments in microarray technology to analyze the complex biology of your tumor and provide you and your physician with powerful insights into the aggressiveness of your cancer.<sup>1-3</sup>

### How will I benefit from MammaPrint?

MammaPrint is a significant advancement toward truly personalized cancer diagnosis and treatment. When used in conjunction with other risk assessment factors, MammaPrint provides new and independent information about your

individual risk and can aide you and your physician in making more informed decisions about the use of hormonal therapy alone, or with chemotherapy.

### How will my doctor use the MammaPrint result for treatment decisions?

Surgeons and oncologists rely on MammaPrint with other clinical criteria to assist in their therapeutic decision making. When combined with traditional risk factors, if you are Low Risk by MammaPrint your doctor may recommend hormonal therapy, which is believed to further reduce your risk. Conversely, if you are High Risk by MammaPrint and have additional risk variables, your doctor may recommend more aggressive therapy which may include chemotherapy.



## What does the MammaPrint® test result mean?

MammaPrint analyzes the 70 critical genes identified in breast cancer metastasis to determine a woman's true risk of recurrence. MammaPrint provides a definitive result of Low Risk or High Risk of metastasis. With MammaPrint, there are no intermediate results, so there is no uncertainty about your personal risk and treatment needs.

### **Low Risk Result:**

A "Low Risk" MammaPrint result means that a patient has a 10% chance that her cancer will recur within 10 years without any additional adjuvant treatment, either hormonal therapy or chemotherapy.<sup>3,4</sup>

### **High Risk Result:**

A "High Risk" MammaPrint result means that a patient has a 29% chance that her cancer will recur within 10 years without any additional adjuvant treatment, either hormonal therapy or chemotherapy.<sup>3,4</sup>

## How was MammaPrint developed?

As reported in *Nature*, MammaPrint was developed on 10 year outcome data from an untreated breast cancer patient population providing an unbiased gene selection. With a small sample of each patient's tumor, our researchers analyzed the entire human genome. After examining approximately 25,000 genes, the most prognostic genes involved in breast cancer metastasis were discovered. Then a precise bioinformatics algorithm was used to determine the 70 gene expression signature.<sup>1</sup>

## What is the added benefit of MammaPrint's microarray technology?

MammaPrint is performed using microarray chip technology, which enables the assessment of the 70-gene profile and has the added benefit of simultaneously researching thousands of additional genes.

In addition to the MammaPrint profile, Agendia analyzes 164 prognostic breast cancer genes, 80 subtyping genes, 56 unique drug target genes, 465 normalization genes and 536 quality control genes — a total of 1,371 individual genes per patient result. Although these extra genes are not currently reported, Agendia is actually documenting the unique characteristics, or "fingerprint," of your tumor.

As the scientific and medical community gains a greater understanding of the role that these supplementary genes play in disease progression and treatment, the data captured may provide the key to an even greater level of personalized medicine for you.

## How does MammaPrint® differ from other laboratory tests?

Only MammaPrint analyzes the 70 critical genes that influence breast tumor progression and the potential for metastasis, giving you and your physician powerful insights into the aggressiveness of your cancer. MammaPrint provides you and your doctor new and independent information distinct from traditional risk assessment criteria, such as age, tumor size and hormonal (ER/PR/HER2) status. MammaPrint has been validated through numerous peer-reviewed, published studies and by the FDA as a highly accurate means of identifying your individual risk of metastasis. MammaPrint provides a definitive result of Low Risk or High Risk of metastasis.<sup>3-11</sup>

## How does MammaPrint differ from genetic testing?

Genetic testing refers to the study of genes and their role in inheritance, the way certain traits or conditions are passed down from one generation to the next. Whereas MammaPrint is a genomic test that analyzes a profile of 70 genes involved in breast cancer metastasis and the activity of those genes. It provides a genomic signature of your complex tumor biology that assesses the risk of your breast cancer returning and helps determine your need for therapy.

## How was MammaPrint validated?

MammaPrint has been independently validated in studies on over 2,375 breast cancer patients at leading US and European cancer centers, with results published in highly respected peer reviewed journals such as the *New England Journal of Medicine*, *Lancet Oncology*, *Journal of the National Cancer Institute*, *Clinical Cancer Research* and *Breast Cancer Research and Treatment*, among others.<sup>4-15</sup>

To date, over 17,500 early stage breast cancer patients like you have chosen MammaPrint to assess their individual breast cancer recurrence risk.

## Why is an FDA cleared test important to me?

Since you and your doctor are making vital treatment decisions based on your test results, the importance of regulatory review and clearance cannot be overstated. MammaPrint's clearance by the United States Food and Drug Administration (FDA) as an In Vitro Diagnostic Multivariate Index Assay (IVDMIA) confers confidence in its safety and effectiveness. The FDA label indicates that as a diagnostic tool, MammaPrint has over a 98% degree of accuracy in classifying patients as Low Risk or High Risk. MammaPrint is the only gene expression breast cancer test currently available in the United States that has met the FDA's strict IVDMIA clearance criteria.<sup>3</sup>

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*“Clearance of the MammaPrint test marks a step forward in the initiative to bring molecular-based medicine into current practice. MammaPrint results will provide patients and physicians with more information about the prospects for the outcome of the disease. This information will support treatment decisions.”*

—Andrew C. von Eschenbach, M.D., Commissioner of Food and Drug Administration





## How do I request MammaPrint®?

During your preliminary consultation, ask your radiologist, surgeon or oncologist if MammaPrint can help you make more informed choices about your treatment options. The discussion about MammaPrint should take place after your mammogram or coinciding with your initial diagnosis of early stage breast cancer.

## When should I request MammaPrint?

The decision to request MammaPrint must be made prior to surgery, allowing for the coordination of tissue sampling and submission for testing. Once you and your doctor have chosen to order the MammaPrint test, your doctor will arrange to obtain a small tissue sample of your tumor during your core needle biopsy procedure or surgery.

## Where is the MammaPrint test performed?

Agendia performs MammaPrint testing at its state-of-the-art CLIA (Clinical Laboratory Improvement Act) certified and CAP (College of American Pathology) registered and compliant genomics laboratories in Irvine, California and Amsterdam, The Netherlands.

## How long will it take for the MammaPrint result?

Agendia understands the urgency of the test result and its impact on treatment decisions. All tests are performed with quick turnaround while maintaining the strictest quality and control measures. Test results are delivered to your doctor within 7-10 days from the date of sample submission.

## Where can I find more information on MammaPrint and breast cancer?

Please contact Agendia Customer Care by email at [customercare@agendia.com](mailto:customercare@agendia.com) or by phone at 1.888.321.2732. Also, please visit our website at [www.agendia.com](http://www.agendia.com).

Web: [www.agendia.com](http://www.agendia.com)

Email: [customercare@agendia.com](mailto:customercare@agendia.com)

Ph: 888.321.2732

## Is there information I can give to my doctor about MammaPrint?

Agendia is pleased to provide your entire breast cancer medical team with more information regarding MammaPrint. You can also refer your physician to our Customer Care staff as well as our website.

Web: [www.agendia.com](http://www.agendia.com)

Email: [customercare@agendia.com](mailto:customercare@agendia.com)

Ph: 888.321.2732

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## Awards & Recognition

Agendia's MammaPrint® has been acknowledged by the medical community as well as other prominent organizations for its role in the advancement of breast cancer research and diagnostics as well as its contributions in the movement toward personalized medicine.

- **2005** – Oprah Winfrey recognized Dr. Laura van 't Veer for her work on MammaPrint as one of the **“Five Biggest Health Breakthroughs by Women Scientists”** in **“O” Magazine**.
- **2007** – **The U.S. Food & Drug Administration granted the first and only IVDMIA clearance to the MammaPrint breast cancer gene expression profile on February 6th.** On June 22nd, Agendia acquired its second FDA clearance for use with its RNARetain® room temperature tissue fixative for molecular testing.
- **2007** – Dr. Laura van 't Veer, Co-founder and Chief Research Officer of Agendia, received the **2007 Breast Cancer Research Foundation Award from the Estee Lauder Pink Ribbon Breast Cancer Research Foundation.**
- **2007** – Dr. Laura van 't Veer received the **2007 European Society of Medical Oncology (ESMO) Lifetime Achievement Award** for her work in translational research in breast cancer and the development of MammaPrint.
- **2007** – **TIME Magazine** chose MammaPrint as one of the **“Five Best Healthcare Inventions of the Year”** naming it **“Cancer's Crystal Ball.”**
- **2007** – **The Frost & Sullivan European Product Innovation Award** in the field of biomarker based breast cancer diagnostics was presented to Agendia for its new method of translating a breast cancer prognosis microarray signature into a high-throughput diagnostic test called MammaPrint.
- **2008** – MammaPrint test declared **“One of the Most Pioneering Healthcare Innovations”** in the 21st Century by the Dutch Government's Healthcare Innovation Platform.
- **2009** – MammaPrint added to the **St. Gallen's International Oncology Guidelines for Primary Therapy of Early Breast Cancer.**



# PEACE OF MIND

MammaPrint® delivers a Low Risk -or- a High Risk result on 100% of the tests performed. —*There are no Intermediate Results.*



“With the recent predictive data on MammaPrint® presented at ASCO, I am confident that patients with breast cancer who are classified as "High Risk" by MammaPrint are likely to benefit from both neoadjuvant and adjuvant chemotherapy. MammaPrint has proven especially valuable in allowing me to personalize my treatment recommendations and engage in more meaningful clinical discussions with my patients about their individual risk of recurrence.”

Christine Dauphine, MD  
*Assistant Professor of Surgery  
David Geffen School of Medicine at UCLA  
Division of Surgical Oncology  
Director of the Breast Clinic  
Harbor-UCLA Medical Center*

*The decision to run MammaPrint  
must be made prior to surgery.  
Ask your doctor today.*

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