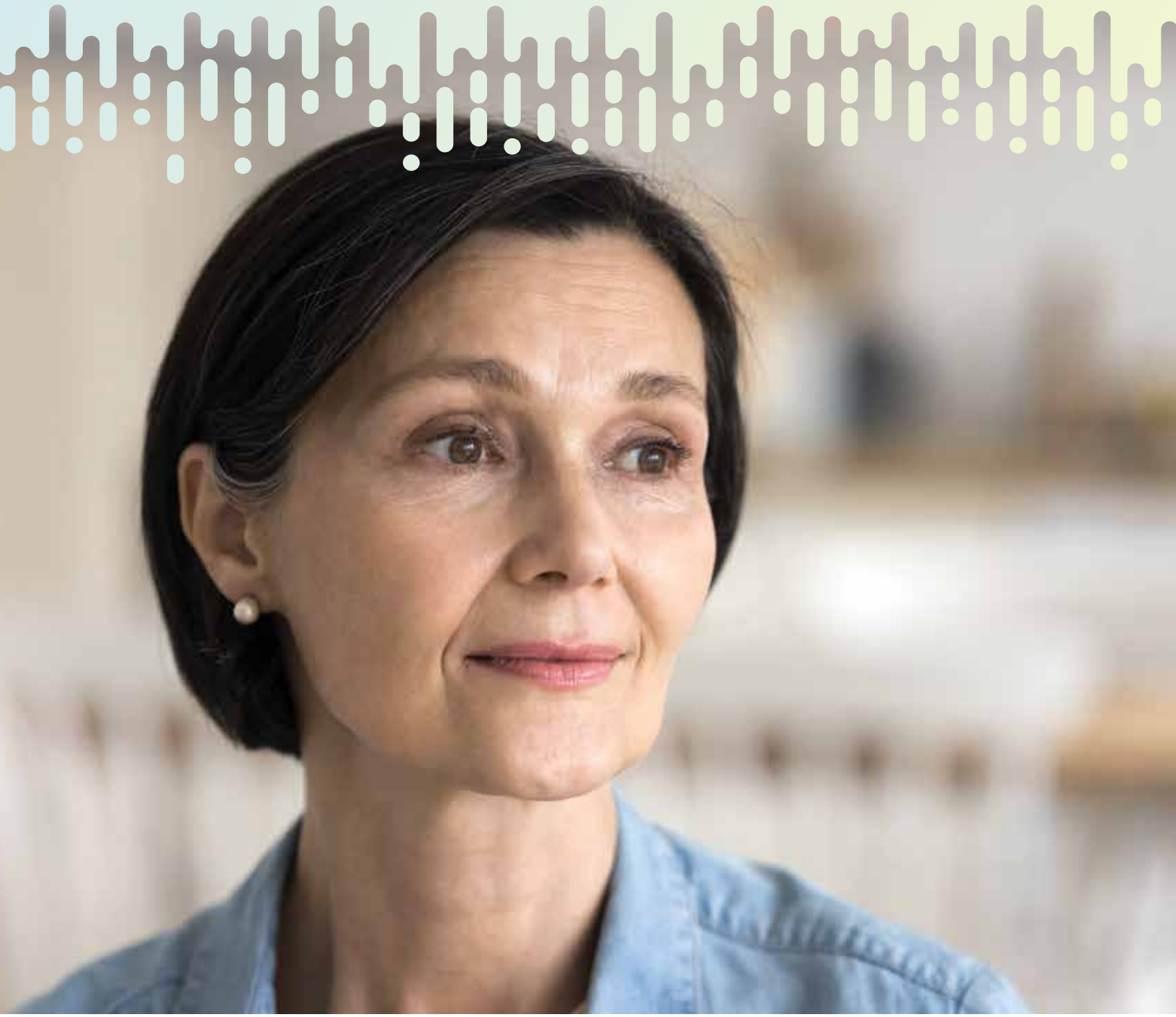
Precision Medicine

Navigating Early Breast Cancer: **Understanding Your Test Results**



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Preparing for Your Next Steps

Your doctor ordered testing to help understand your cancer and come up with a treatment plan. Those tests may include biomarkers, pathology, genomic expression profiling, and/or others.

Explore this brochure as you prepare to receive your test results.

Quick Definition Cheat Sheet

What is a biopsy?

A **biopsy** is a sample of tissue taken from your breast for pathology and/or biomarker testing.[1]

What is a biomarker?

A **biomarker** is a substance that can be found in blood or tissues that signals a normal or abnormal process, or a condition or disease. Examples of biomarkers found in breast cancer are hormone receptors (HR), specifically estrogen receptors or progesterone receptors (ER or PR) and HER2. Your status of these biomarkers is usually found on a pathology report.[1-4]

What is a pathology report?

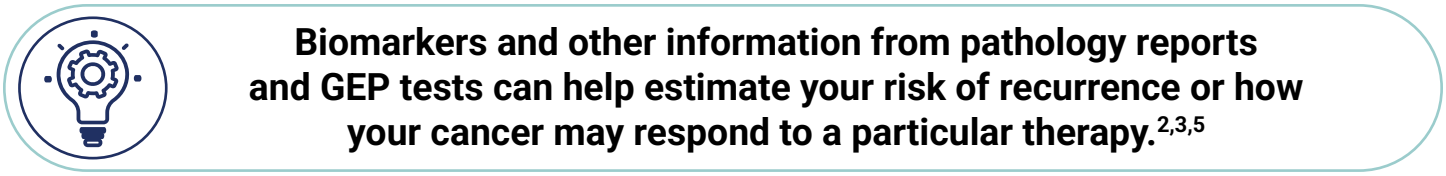
A **pathology report** is a document that details the results of the tests performed on the biopsy sample.[1]

What is genomic expression profiling?

Genomic expression profiling, sometimes referred to as **GEP,** is a special test that reports on the activity of many genes or biomarkers at once and tells doctors how your tumor is behaving. Some examples of GEP tests are Oncotype DX® and MammaPrint®.[1]

What is risk of recurrence?

Risk of recurrence is how likely your cancer is to come back after receiving treatment.[5]



HER2, human epidermal growth factor receptor 2.
Oncotype DX is a registered trademark of Exact Sciences Corporation. **MammaPrint** is a registered trademark of Agendia.

The Path of Your Diagnosis and Biomarker Testing

Sample collection

Tissue from your biopsy is **collected and tested** for biomarkers to help to[1,6]:

- Inform your diagnosis (cancer detection and cancer typing)
- Guide personalized therapy options

Pathology report

Your **pathology report** provides key information about the biology of your cancer.[1,7]

- Key biomarkers such as hormone receptors (HR) and HER2
- Tumor characteristics
- Tumor presence in different tissues

These results help determine the stage of your cancer and help to guide your care options.[1,5]

- The stage of your cancer is usually a number that represents its severity, and is determined by the size of the tumor and if it has spread[1]

GEP

Genomic expression profiling (GEP) is a test which analyzes key biomarkers in your tumor to help predict your risk of cancer recurrence.[5,6,8]

Treatment discussion

You and your care team will use the information from your pathology and GEP results to discuss a **personalized treatment plan**.[5,8]

Talk to your care team to understand where you are in this process and what you can expect to happen next.

HER2, human epidermal growth factor receptor 2.

Breaking Down Your Pathology Report

If you are getting a biopsy here's an example of what a **sample report** may look like.[4,7]

SPECIMEN
Procedure: excision
Laterality: right

TUMOR
Tumor site: upper outer quadrant–2 o'clock
Distance from nipple: 3 cm

HISTOLOGIC TYPE
Invasive carcinoma of no special type (ductal)

HISTOLOGIC GRADE
Glandular/tubular differentiation: score 2
Nuclear pleomorphism: score 3
Mitotic rate: score 3
Overall grade: grade 3
Largest invasive focus: 55 mm

DUCTAL CARCINOMA IN SITU
Not identified

LYMPHATIC/VASCULAR INVASION
Present

REGIONAL LYMPH NODE STATUS
Tumor present in regional lymph nodes
At least 2 positive nodes

SPECIAL STUDIES
Ki-67 proliferative index: 51% to 60%
Estrogen receptor (ER) status: positive
- Average intensity of staining: strong (3+)

Progesterone receptor (PR) status: positive
- Average intensity of staining: strong (3+)

HER2 by immunohistochemistry (IHC) status:
Negative (score 0)

HER2 by in situ hybridization (ISH) status:
Negative (group 5)

Highlighted sections in this hypothetical report explain potential influences on risk of recurrence and treatment options.[1,4,7,*]

*The format of your test results may vary.

Breaking Down Your Pathology Report (continued)

Histologic grade shows the difference between the cancer cells and normal cells and shows how fast the tumor is growing. Tumors with a higher histologic grade have a higher chance of coming back after treatment.[1]

Tumor size is measured at its widest point. Larger tumors may have poorer outcomes, but size alone does not determine risk of recurrence.[5,7]

Lymphatic/vascular invasion shows if the cancer has spread into lymph vessels. **Lymph node status** shows if the cancer is present in nearby lymph nodes. If this occurs, it can mean there is a greater chance of the cancer spreading.[1,5,7]

Ki-67 is a protein that is seen more when cells are growing. Lower scores may mean a slower-growing cancer and potentially a smaller chance that the cancer will spread.[1,5]

Estrogen and progesterone receptors are proteins that respond to hormones. An **ER+** and/or **PR+ status** helps determine what type of treatment you may get or helps determine your risk.[1]

HER2 is also a receptor. A **HER2+ status** also helps determine what type of treatment you may get.[1]

Your pathology report results will be combined with your doctor's assessment and other results to help guide your care plan.[1,5]

Explaining Your GEP Results

Sample Oncotype DX® Report[6,9]

This hypothetical report is based on the Oncotype DX® report. Highlighted sections explain potential influences on risk of recurrence and treatment options.[6,9,*]

*The format of your test results may vary.

Recurrence score (RS) is a result between 0 and 100 based on the specific genes in the tumor. The RS provides the risk of recurrence in the body other than in the breast.[6]

Distant recurrence risk at 5 years shows the risk of recurrence somewhere else in the body within 5 years when treated with hormone therapy (HT) alone.[6,9]

Absolute chemotherapy (CT) benefit is the expected benefit of adding CT to HT based on your RS and age.[6]

Recurrence Score® (RS) result	**16**
Distant recurrence risk at 5 years	With hormone therapy (HT) alone **6%**
Group average absolute chemotherapy (CT) benefit	RS 14–25 **2.7%**

Oncotype DX® defines a high risk of recurrence as an RS of 26 to 100[10]

If you are premenopausal and have an RS result of 25 or lower, consult with your doctor about your specific clinical features and the potential risks and benefits of chemotherapy[10]

Oncotype DX is a registered trademark of Exact Sciences Corporation.
Not all GEP reports are listed.

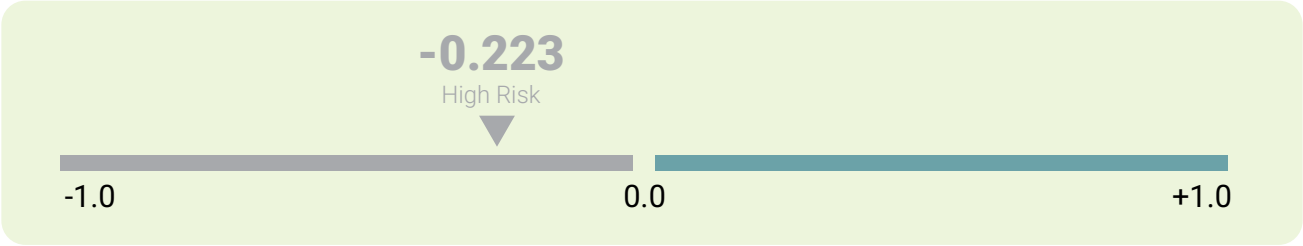
Explaining Your GEP Results (continued)

Sample MammaPrint® Report[11,12]

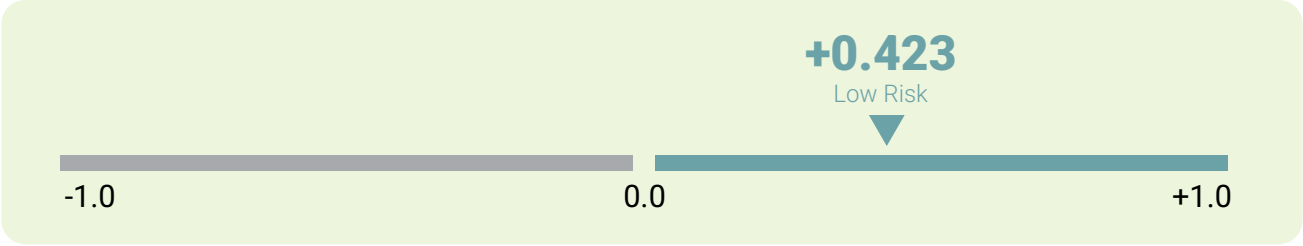
This hypothetical report is based on the MammaPrint® report.[11,12,*]

*The format of your test results may vary.

MammaPrint® report provides a result of either high risk or low risk.[11,12]



There will be standardized text above and below the image on the report that is intended to explain to the doctor how the test was validated.[11,12]



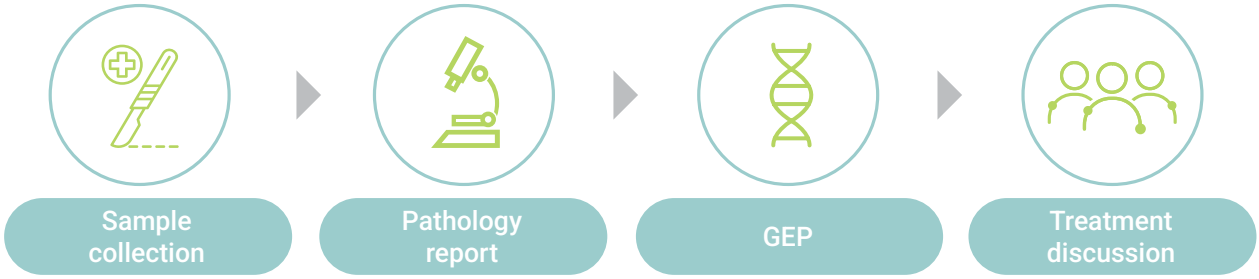
The MammaPrint® analysis is based on several scientific processes to determine the risk of recurrence. The result is an expression profile, or "fingerprint," of the biopsy sample.[13]

Your GEP results combined with your pathological report and physician's assessment will help estimate your risk of recurrence.[14-16]

MammaPrint is a registered trademark of Agendia.
Not all GEP reports are listed.

Discussing Your Results With Your Care Team

You and your care team will work together to consider treatment options from both your pathology and GEP results.[5,8]



Key Discussion Points May Focus on Aspects of Your Pathology and GEP Results That[1,5-7]:

Indicate your risk of recurrence

- Histologic grade
- Tumor size
- Lymphatic/vascular invasion
- Lymph node status
- Ki-67 proliferative index
- GEP recurrence score

Inform your potential treatment course

- ER and PR status
- HER2 status
- Overall risk of recurrence

According to cancer treatment guidelines, the discussion with your care team should also emphasize the **importance of your treatment preferences** as a patient.[8]

Taken together, the information from your pathology and GEP reports will determine your risk of recurrence to **help develop your personalized plan** based on a discussion with your care team.[5,6,8]

Questions for Your Care Team:

What types of tests have already been done?

What additional diagnostic or biomarker tests do you recommend for me?

What is the risk of my cancer coming back?
(This is your recurrence score; it will be either low, intermediate, or high.)

If my recurrence score is intermediate, what does that mean for me?

How do the results of my biomarker tests, including GEP, help with care planning?

NOTES

References: 1. American Cancer Society. Accessed January 15, 2026. https://www.cancer.org/cancer/diagnosis-staging/tests/biopsy-andcytology-tests/understanding-your-pathology-report/breast-pathology/breast-cancer-pathology.html **2.** LUNGevity Foundation. Accessed January 16, 2026. https://www.lungevity.org/sites/default/files/biomarker/biomarker-flyer-052020.pdf **3.** Caris Life Sciences. Accessed January 16, 2026. https://www.carislifesciences.com/patients/fight-cancer-smarter/biomarker/ **4.** College of American Pathologists. Accessed January 16, 2026. https://documents.cap.org/documents/New-Cancer-Protocols-March-2025/Breast.Bmk_1.6.0.0.REL.CAPCP.pdf?_gl=1*19n2xb3*ga*MTg0MzA2ODk4NS4xNzMzMTYxNzc0*_ga_97ZFJSQQ0X*MTc0MzE4NjQ2MS41LjAuMTc0MzE4NjQ2OC4wLjAuMA **5.** Zambelli A, Gallerani E, Garrone O, et al. Working tables on Hormone Receptor positive (HR+), Human Epidermal growth factor Receptor 2 negative (HER2-) early stage breast cancer: Defining high risk of recurrence. *Crit Rev Oncol Hematol*. 2023;191:104104. doi:10.1016/j.critrevonc.2023.104104 **6.** Exact Sciences. Accessed January 16, 2026. https://www.oncotypeiq.com/en-ca/breast-cancer/healthcare-professionals/oncotype-dx-breast-recurrence-score/interpreting-the-results# **7.** College of American Pathologists. Accessed January 16, 2026. https://documents.cap.org/protocols/Breast.Invasive_4.10.0.0.REL.CAPCP.pdf?_gl=1*jak8y*ga*MTg0MzA2ODk4NS4xNzMzMTYxNzc0*_ga_97ZFJSQQ0X*MTc0MzQ0NDc5Ny42LjAuMTc0MzQ0NDc5OC4wLjAuMA **8.** Andre F, Ismaila N, Allison KH, et al. Biomarkers for Adjuvant Endocrine and Chemotherapy in Early-Stage Breast Cancer: ASCO Guideline Update. *J Clin Oncol*. 2022;40(16):1816-1837. doi:10.1200/JCO.22.00069 **9.** Exact Sciences. Accessed January 18, 2026. https://www.exactsciences.com/-/media/project/headless/one-exact-web/documents/products-services/oncotype-breast/providers/node-positive-sample-report.pdf?rev=4b30214355674f839371a1489605d901 **10.** OncoLink. Accessed January 18, 2026. https://www.oncolink.org/print/pdf/2016?print_1996_the_oncotype_dx_breast_recurrence_score.pdf **11.** Agendia. Accessed January 18, 2026. https://agendia.com/wp-content/uploads/2025/07/MKT506V9_MP-High-US.pdf **12.** Agendia. Accessed January 18, 2026. https://agendia.com/wp-content/uploads/2025/07/MKT013V9_MP-Low-US.pdf **13.** Agendia. Accessed January 18, 2026. https://www.agendia.com/media/M-USA-057-V1_MammaPrint-Physicians-Brochure-FF.pdf **14.** Qian Y, Daza J, Itzel T, et al. Prognostic Cancer Gene Expression Signatures: Current Status and Challenges. *Cells*. 2021;10(3):648. doi:10.3390/cells10030648 **15.** Crolley VE, Marashi H, Rawther S, et al. The impact of Oncotype DX breast cancer assay results on clinical practice: a UK experience. *Breast Cancer Res Treat*. 2020;180(3):809-817. doi:10.1007/s10549-020-05578-6 **16.** Sparano JA, Crager MR, Tang G, Gray RJ, Stemmer SM, Shak S. Development and Validation of a Tool Integrating the 21-Gene Recurrence Score and Clinical-Pathological Features to Individualize Prognosis and Prediction of Chemotherapy Benefit in Early Breast Cancer. *J Clin Oncol*. 2021;39(6):557-564. doi:10.1200/JCO.20.03007 **17.** American Cancer Society. Accessed January 18, 2026. https://www.cancer.org/cancer/managing-cancer/making-treatment-decisions/making-decisions.html#:~:text=feel%20good%20about.-,Making%20a%20treatment%20decision,in%20Seeking%20a%20Second%20Opinion

Summary

Informed
Pathology and GEP reports provide key **information** on your tumor characteristics and biomarker status to help **understand your risk of recurrence and likelihood of responding to chemotherapy.**[1,5,6,8]

Empowered
Understanding your test results **empowers** you to **be involved in shared decision-making with your care team.**[17]

Personalized
Taken together, the findings you discuss with your care team will **provide insight into your personalized treatment options.**[5,8]

Are you interested in learning more about **Precision Medicine?**

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