Veracyte Announces Commercial Launch of the Prosigna Breast Test in the U.S.

June 1, 2026

Genomic test using whole-transcriptome next-generation sequencing technology will be available to order on June 8

The Prosigna test predicts chemotherapy benefit and quantifies 10-year risk of recurrence to help personalize treatment decisions in patients with early-stage breast cancer

SOUTH SAN FRANCISCO, Calif.--(BUSINESS WIRE)--Jun. 1, 2026-- On the heels of the landmark OPTIMA trial readout presented at the ASCO Annual Meeting, Veracyte, Inc. (Nasdaq: VCYT), a leading cancer diagnostics company, today announced the U.S. commercial launch of the Prosigna® Breast Risk of Recurrence (ROR) test, a genomic test for patients diagnosed with early-stage hormone-receptor positive (HR+) breast cancer. The Prosigna test determines a patient's ROR score and estimates the 10-year probability of distant recurrence, providing prognostic insight into how a patient's cancer may behave over time. These insights also help guide treatment decisions, including predicting whether high risk patients are likely to benefit from chemotherapy or may safely achieve optimal outcomes with endocrine therapy alone, enabling clinicians to make personalized care plans for their patients. The Prosigna test will be available to order starting June 8, 2026.

"Every patient diagnosed with breast cancer deserves answers they can trust about what their cancer means and what comes next," said John Leite, PhD, chief commercial officer, Veracyte. "Prosigna gives patients and their oncologists a deeper understanding of their individual risk of recurrence, and, for many, whether chemotherapy will truly benefit them or whether they can safely avoid it. That kind of personalized insight can bring greater confidence and reassurance as patients navigate decisions that will shape their care and future health."

In the U.S., more than 225,000 new HR+/HER2- breast cancer cases are diagnosed each year. When breast cancer is diagnosed early and treated appropriately, five-year survival rates reach 92%.[1] It is critically important to accurately determine a patient's risk of recurrence because the effects of treatment escalation or de-escalation have a lasting impact on a patient's life.

Introducing the Prosigna Test: Prediction that adds up

The Prosigna test is the only breast cancer test that factors a patient's biological, clinical, and pathological information into a single comprehensive analysis. The test uniquely combines intrinsic subtypes and proliferation score with clinical factors to determine a patient's ROR score and predict the 10-year probability of distant recurrence. This long-term risk assessment provides clinically meaningful insight beyond initial diagnosis, particularly in early-stage breast cancer where recurrence can occur many years later.

For decades, clinical risk factors have been a key factor in treatment decisions. Currently, for many patients with high-risk breast cancer who are premenopausal and node positive, standard of care is still chemotherapy and endocrine therapy. New data from the OPTIMA trial shows that nodal involvement and other clinical risk factors do not automatically equate to high risk of recurrence -- for the first time, more than two-thirds of node-positive patients who previously might have received chemotherapy can now safely avoid it based on the Prosigna test results.

Why the Prosigna test stands apart:

- **Comprehensive molecular analysis**: The Prosigna test was developed from the PAM50 genomic classifier, a foundation for understanding breast cancer biology, which classifies a patient's individual tumor into one of the four intrinsic subtypes. The Prosigna test is the only test that combines intrinsic subtypes and proliferation score with clinical pathological factors to provide a comprehensive 10-year probability of distant recurrence.
- **Proven across high-risk populations:** The Prosigna test is the only test proven to be predictive for chemotherapy benefit decisions in a phase III prospective trial for premenopausal and postmenopausal women with high-risk breast cancer, including those with extensive nodal involvement (up to 9 positive nodes).
- **Superior prognostic accuracy:** Extensively validated clinical evidence demonstrates that the Prosigna test is more prognostically accurate than other genomic assays, particularly in the critical 5-10 year breast cancer recurrence window.[2,3]

"The PAM50 signature was designed to unlock the clinical utility of modern biological insights into the nature of breast cancer. Through the Prosigna test, these biological insights are now directly informing treatment decisions for patients," said Matthew Ellis, M.D., Ph.D., one of the developers of the PAM50-based Prosigna test. "The OPTIMA results reinforces the need to ground critical decisions upon tumor biology because understanding risk of recurrence and chemotherapy benefit as distinct principles produces safer and more personalized care."

"Patients diagnosed with early-stage breast cancer deserve access to the most advanced testing available, with the most up to date evidence, so they can make informed treatment decisions with their medical oncology team," said Jean Sachs, MSS, MLSP Chief Executive Officer of Living Beyond Breast Cancer. "Prosigna's ability to accurately predict risk of recurrence means patients may have the option to avoid chemotherapy and its significant side effects or confidently pursue more aggressive treatment when it will truly benefit them. That is what we want for everyone diagnosed with breast cancer – a personalized treatment plan that is informed by the most up-to-date data."

Veracyte is committed to making the Prosigna test accessible to all eligible breast cancer patients. The test is currently covered by most commercial payers, and patients may qualify for financial assistance or a tailored payment plan supported by the Veracyte Access Program for eligible uninsured and underinsured patients. The Prosigna test will be available for ordering starting June 8, 2026 through Veracyte's network nationwide via the easy-to-use Veracyte Ordering Portal. For ordering information and clinical resources, visit www.veracyte.com/prosigna.

Veracyte

Veracyte (Nasdaq: VCYT) is a global diagnostics company with a vision to transform cancer care for patients around the world. The company's molecular tests assess the unique biology of each patient's tumor to help clinicians answer essential questions about cancer care. Veracyte's

Diagnostics Platform combines broad genomic and clinical data, advanced bioinformatics and AI, and a powerful evidence-generation engine to support continued innovation and pipeline development. The company's portfolio includes the Afirma® Genomic Sequencing Classifier test, Decipher® Bladder Genomic Classifier test, Decipher® Prostate Genomic Classifier test, Prosigna® Breast Risk of Recurrence test, and the TrueMRD™ Monitoring Test for MIBC. For more information, visit Veracyte's website or follow the company on LinkedIn or X (Twitter).

Cautionary Note Regarding Forward-Looking Statements

This press release contains forward-looking statements, including, but not limited to, statements regarding the potential clinical utility, impact, and benefits of Veracyte's Prosigna® Breast Risk of Recurrence (ROR) test; the ability of the Prosigna Breast Test to guide adjuvant chemotherapy decisions in early-stage hormone-receptor positive (HR+) patients, including identifying patients who may safely avoid chemotherapy and its side effects without compromising outcomes; the extent to which the results of the OPTIMA trial may influence clinical decision-making; the potential for molecular testing to inform treatment decisions based on tumor biology; and the adoption, use and availability of the Prosigna test and the availability of payer coverage, financial assistance programs, and patient access to the Prosigna test. Forward-looking statements can be identified by words such as "appears," "anticipate," "intend," "plan," "expect," "believe," "should," "may," "will," "enable," "positioned," "offers," "designed," "ultimately," and similar references to future periods. Actual results may differ materially from those projected or suggested in any forward-looking statements. These statements involve risks and uncertainties that could cause actual results to differ materially from our predictions. Additional factors that may impact these forward-looking statements can be found under the caption "Risk Factors" in our Annual Report on Form 10-K filed on February 26, 2026, as well as in other documents that we may file from time to time with the Securities and Exchange Commission. Copies of these documents, when available, may be found in the Investors section of our website at investor.veracyte.com. These forward-looking statements speak only as of the date hereof and, except as required by law, we specifically disclaim any obligation to update these forward-looking statements or the reasons why actual results might differ, whether as a result of new information, future events, or otherwise.

References:

1. National Breast Cancer Foundation, Inc., Breast Cancer Facts & Stats; Last updated Apr 20, 2026. https://www.nationalbreastcancer.org/breast-cancer-facts/#mortality.
2. Dowsett M, et al. J Clin Oncol. 2013;31(22):2783-2790.
3. Sestak et. al., JNCI (2013);105(19).

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