



NEWS RELEASE

# SignateraTM Genome Clinical Performance Highlighted at ASCO 2025

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Overall pan-cancer sensitivity of 94% and specificity of 100%, with analytical detection down to 1 PPM

AUSTIN, Texas--(BUSINESS WIRE)-- **Natera, Inc.** (NASDAQ: NTRA), a global leader in cell-free DNA and precision medicine, announced results from a large-scale pan-cancer study of its Signatera Genome assay, which was presented today, June 2nd, at the 2025 American Society of Clinical Oncology (ASCO) Annual Meeting.

The study analyzed the performance of Signatera Genome in a cohort of 392 patients (> 2,600 plasma samples) across five different tumor types (breast cancer, non-small cell lung cancer, melanoma, renal cell carcinoma, and colorectal cancer). Key results included:

- Excellent pan-cancer performance: Signatera Genome demonstrated overall longitudinal sensitivity of 94% and specificity of 100% across 5 cancer types. Longitudinal sensitivity was 100% in lung cancer and renal cancer, and post-surgical landmark sensitivity was over 70% in both lung cancer and breast cancer.
- Ultrasensitive detection: In the surveillance setting, nearly 50% of Signatera-positive cases were detected in the ultra-sensitive range ( $\leq 100$  parts per million).
- Highly predictive of long-term outcomes: In the pan-cancer cohort, patients who tested Signatera-negative had excellent prognosis, with 100% distant relapse-free survival (DRFS) at 12 months and 99% at 24 months. In contrast, Signatera-positive patients faced a markedly higher risk of recurrence, with DRFS dropping to 41% at 12 months and just 14% at 24 months.
- Extended lead times: Signatera Genome detected recurrence 3 months earlier, on average, compared to the Signatera Exome assay.

- Demonstrates Signatera's potential to identify which patients may benefit from adjuvant therapy: Among Signatera-positive patients, those who received adjuvant therapy had significantly improved outcomes, with a 12-month DRFS of 83% compared to 49% for those who did not receive therapy. For Signatera-negative patients, there was no meaningful benefit from adjuvant therapy with a 12-month DRFS of 93% (treated) vs. 98% (observation).

"These results highlight that our ultra-sensitive Signatera Genome assay not only enables detection of ctDNA at extremely low levels, but also provides powerful insights into patient prognosis and treatment response," said Alexey Aleshin, M.D., MBA, corporate chief medical officer and general manager of oncology at Natera. "This is one of the largest MRD studies of a genome tumor-informed MRD assay, and reinforces the excellent performance of Signatera across a wide range of solid tumors."

## About Signatera

**Signatera** is a personalized, tumor-informed, molecular residual disease test for patients previously diagnosed with cancer. Custom-built for each individual, Signatera uses circulating tumor DNA to detect and quantify cancer left in the body, identify recurrence earlier than standard of care tools, and help optimize treatment decisions. The test is available for clinical and research use and has coverage by Medicare across a broad range of indications. Signatera has been clinically validated across multiple cancer types and indications, with published evidence in more than 100 peer-reviewed papers.

## About Natera

Natera™ is a global leader in cell-free DNA and genetic testing, dedicated to oncology, women's health, and organ health. We aim to make personalized genetic testing and diagnostics part of the standard-of-care to protect health and inform earlier, more targeted interventions that help lead to longer, healthier lives. Natera's tests are supported by more than 250 peer-reviewed publications that demonstrate excellent performance. Natera operates ISO 13485-certified and CAP-accredited laboratories certified under the Clinical Laboratory Improvement Amendments (CLIA) in Austin, Texas, and San Carlos, California. For more information, visit [www.natera.com](http://www.natera.com).

## Forward-Looking Statements

All statements other than statements of historical facts contained in this press release are forward-looking statements and are not a representation that Natera's plans, estimates, or expectations will be achieved. These forward-looking statements represent Natera's expectations as of the date of this press release, and Natera disclaims any obligation to update the forward-looking statements. These forward-looking statements are subject to known and unknown risks and uncertainties that may cause actual results to differ materially, including with

respect to whether the results of clinical or other studies will support the use of our product offerings, the impact of results of such studies, our expectations of the reliability, accuracy and performance of our tests, or of the benefits of our tests and product offerings to patients, providers and payers. Additional risks and uncertainties are discussed in greater detail in "Risk Factors" in Natera's recent filings on Forms 10-K and 10-Q and in other filings Natera makes with the SEC from time to time. These documents are available at [www.natera.com/investors](http://www.natera.com/investors) and [www.sec.gov](http://www.sec.gov).

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