



BillionToOne's Northstar Response® Validated in New Peer-Reviewed Study, Building on Previous Clinical Research

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Proprietary & Patented QCT™ Technology-Powered Methylation Approach Enables Up to 10x More Precise Treatment Response Monitoring Than Alternative Blood-Based Methods

MENLO PARK, Calif., March 3, 2025 /PRNewswire/ -- [BillionToOne](#), a molecular diagnostics company with a mission to create powerful and accurate tests that are accessible to all, announced today the publication of a peer-reviewed study in [Nature Scientific Reports](#)¹ validating Northstar Response®, BillionToOne's novel tissue-free ctDNA liquid biopsy test that enables physicians to monitor cancer treatment response in Stage III-IV cancers with unprecedented precision and convenience from a simple blood draw. This pan-cancer analytical validation follows the recent publication of a separate clinical validity and utility study in [Clinical Lung Cancer](#)² that examined the correlation between Tumor Methylation Scores (TMS) and therapy response in a real-world setting that successfully predicted anti-PD1/immunotherapy response in late-stage NSCLC patients.

Northstar Response is transforming cancer care by bringing the precision of single-molecule quantification into treatment response monitoring through a simple, non-invasive blood test. This pan-cancer assay enables physicians to longitudinally monitor a patient's response to therapy by measuring how cancer detected in the blood changes over time, providing a quantifiable measure of treatment effectiveness that can detect subtle changes with remarkable precision.

"Traditional methods for monitoring cancer treatment response, such as imaging, are limited by infrequent testing schedules, inability to detect subtle tumor changes, and other problems such as pseudo-progression," said Gary Palmer, Chief Medical Officer, Oncology at BillionToOne. "Northstar Response can measure tumor burden at the molecular level, adding an unprecedented level of precision to cancer monitoring. Northstar Response's precise quantification of the tumor burden is an important aspect for therapy response monitoring in late-stage cancers. It is differentiated compared to minimal residual disease (MRD) assays that are typically designed for Stage I-II cancers with fundamentally qualitative ctDNA positive/negative assessments."

The assay's foundation is BillionToOne's patented Quantitative Counting Template™ (QCT™) technology, which acts as a "molecular ruler" that enables absolute quantification down to a [single molecule level](#),³ bringing new precision to NGS-based analysis in molecular diagnostics. When applied to Northstar Response, this translates to the ability to accurately discriminate between small differences in ctDNA burden with high precision (i.e. tumor fraction changes as small as 0.25%).

In a previous study² with advanced NSCLC patients with longitudinally banked plasma sample, Northstar Response's changes in TMS measured 4-10 weeks after starting anti-PD1 based immunotherapy treatment significantly predicted real-world progression free survival (rwPFS, $P < 0.0001$), compared to standard imaging assessments which did not reach statistical significance ($P = 0.55$). The study showed that the test reliably detected treatment response and progression earlier than CT scans, with high concordance between TMS and clinical outcomes. The current study analytically validates the pan-cancer nature and design of the Northstar Response across 12 cancer types, including lung, colorectal, and pancreatic cancers. It is being followed up by additional clinical validity and utility studies that can further demonstrate the unique role that Northstar Response can play in shaping cancer care across all solid tumor and treatment paradigms.

Unlike tumor-informed tests that require invasive biopsies and create a rigid mutation profile known at the time of diagnosis, or other SNV/VAF based tests that track only a limited number of genomic targets, Northstar Response monitors hundreds of cancer-specific methylation sites only using blood samples. This method can enable a more robust approach to monitoring, given the rapid evolution of tumors in late-stage cancers under systemic therapy. The test's Tumor Methylation Scores correlate with clinical outcomes, which can potentially allow physicians to detect treatment resistance significantly earlier than conventional imaging.

For more information about Northstar Response®, visit northstaronc.com.

About BillionToOne

Headquartered in Menlo Park, California, BillionToOne is a precision diagnostics company on a mission to make molecular diagnostics more accurate, efficient, and accessible for all. The company's patented Quantitative Counting Templates™ (QCT™) molecular counting platform is the only multiplex technology that can accurately count DNA molecules at the single-molecule level. For

more information, please visit www.billiontoone.com.

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¹ Ye, P.P., Viens, R., Shelburne, K.E. et al. Molecular counting enables accurate and precise quantification of methylated ctDNA for tumor-naive cancer therapy response monitoring. Sci Rep 15, 5869 (2025). <https://doi.org/10.1038/s41598-025-90013-3>

² Hsiao, Angela et al. Brief Report: Methylation-Based ctDNA Serial Monitoring Correlates With Immunotherapy Response in NSCLC. Clinical Lung Cancer, Volume 26, Issue 1, 72 - 77

³ Tsao, D.S., Silas, S., Landry, B.P. et al. A novel high-throughput molecular counting method with single base-pair resolution enables accurate single-gene NIPT. Sci Rep 9, 14382 (2019). <https://doi.org/10.1038/s41598-019-50378-8>

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