



BillionToOne Launches Northstar Origin, a New Liquid Biopsy Test to Help Identify Tissue of Origin

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New add-on test from a single blood draw; BillionToOne also expands Northstar Select® panel to 102 genes

MENLO PARK, Calif., Sept. 1, 2026 /PRNewswire/ -- BillionToOne, Inc. (Nasdaq: BLLN), a next-generation molecular diagnostics company with a mission to create powerful and accurate tests that are accessible to all, today announced the launch of Northstar Origin™, a new liquid biopsy add-on test for tissue-of-origin prediction, along with the expansion of its Northstar Select® panel from 84 to 102 genes to cover genes that are included in recent and upcoming FDA approvals.



Northstar Origin is a physician-ordered add-on test to Northstar Select that predicts tissue of origin directly from circulating cell-free DNA (cfDNA) for patients with cancer of unknown primary (CUP) or uncertain cancer diagnosis, reducing the need for additional tissue or separate blood draws. The assay combines methylation profiling with the same single-molecule precision used in Northstar Response® with an independent signal obtained from tissue-specific somatic variants detected by Northstar Select.

Northstar Origin addresses a persistent diagnostic challenge for community oncologists: uncertain tumor origin. Roughly 3-5%¹ of new oncologic diagnoses present as CUP, where standard pathology and imaging workup cannot confidently identify a definitive tumor source, complicating therapy selection. Moreover, up to ~10% of patients in community oncology settings without access to detailed pathology work-ups may have uncertain diagnoses². Tissue-based tools for resolving these cases can also be limited by the amount and quality of tissue available.

"Community oncologists are often asked to make the same complex diagnostic decisions as physicians at academic centers, without the same access to tumor boards or subspecialty pathology support," said Ethan Dmitrovsky, MD, Chief Medical Officer, Oncology at BillionToOne. "Northstar Origin is designed to help close that gap. It is a highly accurate, easy-to-use diagnostic aid that can be added to the liquid biopsy a patient already receives for therapy selection. Northstar Origin can extend more equitable access to care."

Northstar Origin's performance was evaluated in an independent validation cohort of 1,578 patients, after the supervised classifier was developed using 6,025 blood samples from advanced cancer patients previously submitted to BillionToOne's clinical laboratory. In this evaluation, the model identified the correct tissue of origin as its top prediction in 87% of cases, and within its top three predictions in 91% of cases³. BillionToOne plans prospective studies to expand the model to additional tumor types and further evaluate its clinical utility.

Allen Chen, MD, Vice President of Oncology Clinical Development and Medical Affairs at BillionToOne and senior author of the study, said the findings underscore the clinical importance of resolving a tumor's primary site. "Cancers of unknown primary have historically posed a challenge because not knowing where the tumor originated leads to treatment uncertainty and patient anxiety. In these scenarios, conventional workup, including physical examination, imaging, and pathology, is unfortunately often not enough. Northstar Origin provides clinicians with an additional, complementary molecular prediction from the same blood sample used for therapy selection. Studies have consistently shown that uncovering the primary site results in more personalized therapy and better outcomes."

BillionToOne also announced the expansion of Northstar Select, its comprehensive genomic profiling liquid biopsy for therapy selection in advanced solid tumors, from 84 to 102 genes while maintaining its market-leading sensitivity. The expanded panel adds 18 new genes, including MTAP deletion, an emerging biomarker of increasing clinical relevance, and a copy number loss biomarker that is typically difficult for liquid biopsy assays to detect.

About Northstar Origin™

Northstar Origin is BillionToOne's liquid biopsy add-on test that predicts tissue of origin from circulating cell-free DNA, without requiring additional tissue or a separate blood draw. In a validation study of 1,578 patients, Northstar Origin identified the correct tissue of origin as the top prediction in 87% of cases and within the top three predictions in 91% of cases.³ Northstar Origin is ordered as an add-on at the time of Northstar Select testing and is intended to complement, not replace, pathology and the broader clinical picture.

About Northstar Select®

Northstar Select, BillionToOne's highly sensitive comprehensive genomic profiling (CGP) liquid biopsy assay, now profiles 102 genes and demonstrated superior performance in detecting more clinically actionable alterations in circulating tumor DNA (ctDNA) compared to other liquid biopsy tests on the market. In a prospective head-to-head comparison study which included 182 patients with more than 17 solid tumor types, Northstar Select detected 51% more clinically actionable or pathogenic single nucleotide variant (SNV)/Indels and 109% more copy number variants (CNVs) than the aggregated results from available comparators, with 45% fewer null reports.⁴

About BillionToOne

Headquartered in Menlo Park, California, BillionToOne is a next-generation molecular diagnostics company with a mission to create powerful and accurate tests that are accessible to 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, visit www.billiontoone.com.

Disclaimer

Northstar Select, Northstar Origin, and Northstar Response may produce false-positive or false-negative results. Test results are not a guarantee of the presence or absence of disease and should not be used as the sole basis for medical decision-making. Northstar Origin results should be interpreted in conjunction with the patient's clinical presentation, pathology, and other diagnostic information; Northstar Origin is intended to complement, not replace, pathologic determination of tissue of origin. Northstar Select, Northstar Origin, and Northstar Response are laboratory-developed tests (LDTs) performed in a CLIA-certified and CAP-accredited laboratory. These tests have not been cleared or approved by the U.S. Food and Drug Administration (FDA). Test performance may vary based on factors including cancer type, disease burden, treatment, and specimen characteristics.

Forward-Looking Statements

This press release contains certain forward-looking statements within the meaning of federal securities laws. These forward-looking statements generally are identified by the words "believe," "project," "expect," "anticipate," "estimate," "intend," "strategy," "future," "opportunity," "plan," "may," "should," "will," "would," "will be," "will continue," "will likely result," and similar expressions. Forward-looking statements are predictions, projections and other statements about future events that are based on current expectations and assumptions and, as a result, are subject to risks and uncertainties. Forward-looking statements in this press release include, but are not limited to, statements regarding the performance of Northstar Origin in the clinical setting. These statements are based on management's current expectations, forecasts and assumptions, and actual outcomes and results could differ materially from these statements due to a number of factors, some of which are beyond BillionToOne's control. These and additional risks and uncertainties that could affect BillionToOne's financial and operating results and cause actual results to differ materially from those indicated by the forward-looking statements made in this press release. These risks and uncertainties include, but are not limited to, those discussed under the captions "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operation" and elsewhere in its Annual Report on Form 10-K, most recently filed Quarterly Report on Form 10-Q, and other filing we make with the Securities and Exchange Commission from time to time. The forward-looking statements in this press release are based on information available to BillionToOne as of the date hereof, and BillionToOne disclaims any obligation to update any forward-looking statements provided to reflect any change in its expectations or any change in events, conditions, or circumstances on which any such statement is based, except as required by law. These forward-looking statements should not be relied upon as representing BillionToOne's views as of any date subsequent to the date of this press release.

1. Spurgeon L, Mitchell C, Cook N, Conway A-M. Cancer of unknown primary: the hunt for its elusive tissue-of-origin – is it time to call off the search? *Br J Cancer*. 2025;133:733-742. doi:10.1038/s41416-025-03073-7

2. BillionToOne qualitative physician research, 2025–2026.

3. Cooper, R., Chopra, M., Huland, D., Zhou, W., Chen, A. Integrated cfDNA Methylation and Genomic Profiling Enables Tissue-of-Origin Prediction from a Single Liquid Biopsy. Abstract submitted for presentation, 6th Binaytra Precision Oncology Summit, 2026. BillionToOne data on file.

4. Bower, X., Wignall, J., Varga, M.G., et al. Validation of a liquid biopsy assay with increased sensitivity for clinical comprehensive genomic profiling. *The Journal of Liquid Biopsy*. <https://doi.org/10.1016/j.jlb.2025.100322>. Head-to-head improvement % determined when compared to comparator products in the aggregate. Actual percentages may vary depending on the individual comparator liquid biopsy test.

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