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Illumina introduces the first distributed whole-genome sequencing solution for highly sensitive MRD research

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An advanced research workflow for fast, flexible detection of molecular residual disease during and following treatment

Solution is the first in a new WGS oncology portfolio, building on Illumina's history of leadership as foundation for MRD market

SAN DIEGO, May 28, 2026 /PRNewswire/ -- Illumina, Inc. (NASDAQ: ILMN) today announced a new complete solution for molecular residual disease (MRD) research based on whole-genome sequencing (WGS). As a distributed kit, it will enable more labs to adopt MRD detection for clinical research. Now in early access for select clinical research partners, the MRD solution is the first whole-genome kit with flexibility to enable solid tumor MRD and blood cancer genomic profiling. It is the first in a new portfolio of WGS oncology research offerings, with additional solutions in development leveraging the latest advancements of the NovaSeq X™.

"In precision healthcare, early and accurate detection of molecular residual disease is critical to monitoring patients during and after cancer treatment," said Todd Christian, senior vice president of Services, Arrays and Genomic Access at Illumina. "Illumina's MRD solution for clinical research leverages the advanced sensitivity of whole-genome sequencing, coupled with unparalleled analysis, to enable our customers to more easily deliver the most precise information to advance MRD research. We aim to make WGS in oncology more accessible and scalable to support the integration of precision solutions into the standard of care."

The MRD solution supports "fingerprinting" through solid tumor samples, and MRD detection using blood samples, all compatible on NovaSeq Systems. The end-to-end research workflow can be completed in as fast as 5 days and is optimized for analytical sensitivity as low as 10 ppm, particularly important for early-stage and low-shedding tumors, including breast, ovarian, and renal.

Illumina's first-of-its-kind DRAGEN™ MRD analysis connects each fingerprint to serial circulating tumor DNA (ctDNA), offering customers flexible workflow combinations to meet their specific needs. Leveraging DRAGEN's unparalleled speed and accuracy, the new MRD solution has been optimized across thousands of samples to develop and demonstrate a ctDNA detection algorithm with 99.5% analytical specificity to distinguish true tumor signals from background noise.

Early adopters see strong performance with Illumina's WGS oncology solution

Several academic institutes evaluated the workflow. Mayo Clinic evaluated the solution[i] on a small sample cohort and found high concordance among previously characterized paired samples. The results were also highly correlated with clinical and imaging results over time. The team is planning to expand the cohort for additional research with Mayo Clinic and other academic partners.

"We are looking forward to participating in early access and evidence generation for a tumor-informed, non-bespoke whole-genome sequencing approach to MRD," said Gang Zheng, MD, PhD and professor of Laboratory Medicine and Pathology at Mayo Clinic. "We have seen early pilot results across several solid tumor clinical samples that demonstrated the potential utility of highly sensitive solid tumor MRD detection, and we continue to pilot technologies that help us efficiently progress in our ability to analyze and translate complex genomic arrays."

Illumina and Bristol Myers Squibb will jointly present a poster at the 2026 American Society of Clinical Oncology (ASCO) Annual Meeting on Sunday, May 31, from 9:00 a.m. to 12:00 p.m. (abstract ID 8591, poster board #381, Lung Cancer: Non–Small Cell Metastatic track). More information can be found at this link.

Roadmap to achieve ultra-sensitivity tailored for broader adoption

Built on recently announced NovaSeq X advancements, including 35B output and Q70 quality scores, a complementary research workflow that will deliver ultra-sensitive MRD detection in the single-digit ppm range leveraging duplex reads is currently in development.

"Illumina continues to push the NovaSeq X's capabilities to help our customers break barriers and unlock more discoveries," said Steve Barnard, PhD, chief technology officer of Illumina. "The new portfolio will bring advanced MRD research directly into labs with unmatched speed and sensitivity. The NovaSeq X is built for the long term, and Illumina will continue to deliver technologies that empower our customers to accelerate oncology breakthroughs."

Illumina technology also fuels centralized MRD providers leading the market today. The NovaSeq X offers foundational capabilities to support the quality, reliability, and scale needed as MRD adoption continues to grow. Illumina's new oncology portfolio builds upon the unique, integrated insight ecosystem of workflows, data and community across genomic, multiomic, and clinical research applications—anchored on the NovaSeq X.

Illumina's MRD research solution is available today for early access to select partners and will launch for global customers next year. Learn more here.

Use of forward-looking statements
This release may contain forward-looking statements that involve risks and uncertainties. Among the important factors to which our business is subject that could cause actual results to differ materially from those in any forward-looking statements are: (i) [ii]our ability to successfully implement NovaSeq X updates on a cost-effective and timely basis, (ii) challenges inherent in developing and launching new products and services, including modifying and scaling manufacturing operations, and reliance on third-party suppliers for critical components; (iii) our ability to manufacture robust instrumentation and consumables and develop reliable software solutions; and (iv) the acceptance and adoption by customers of our newly launched or updated products, which may or may not meet our expectations and theirs, together with other factors detailed in our filings with the Securities and Exchange Commission, including our most recent filings on Forms 10-K and 10-Q, or in information disclosed in public conference calls, the date and time of which are released beforehand. We undertake no obligation and do not intend to update these forward-looking statements, to review or confirm analysts' expectations, or to provide interim reports or updates on the progress of the current quarter.

About Illumina
Illumina is improving human health by unlocking the power of the genome. Our focus on innovation has established us as a global leader in DNA sequencing and array-based technologies, serving customers in the research, clinical, and applied markets. Our products are used for applications in the life sciences, oncology, reproductive health, agriculture, and other emerging segments. To learn more, visit illumina.com and connect with us on X, Facebook, LinkedIn, Instagram, TikTok, and YouTube.

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[i] As an early user, Mayo Clinic independently executed and evaluated the assay in their lab.

[ii] As of the Q4 financial disclosures, the NovaSeq X active install base was 890 at the end of FY2025.

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