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Illumina advances MRD research portfolio with ultrasensitive duplex sequencing technology

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Early access program launches to support ultrasensitive research into molecular residual disease and tumor evolution.

New chemistry is optimized for highest possible accuracy, with reproducible detection of ctDNA at 2.5 parts per million levels with low sample input (10 nanograms) in representative studies

SAN DIEGO, Nov. 9, 2026 /PRNewswire/ -- Illumina, Inc. (NASDAQ: ILMN) today announced an expansion of its molecular residual disease (MRD) research portfolio with an early access program for an ultrasensitive sequencing workflow. Designed to detect trace amounts of circulating tumor DNA (ctDNA) in plasma samples, the workflow's duplex chemistry analyzes both strands of a DNA molecule to increase confidence in detection. It combines the latest sequencing and software advances from the NovaSeq X platform and DRAGEN bioinformatics software to support longitudinal, whole-genome studies of MRD.

"Researchers need effective ways to find the faintest traces of tumor DNA—signals that can be especially difficult to detect in early-stage, low-shedding, or low-mutation-burden tumors," said Cande Rogert, vice president, Global Head of Advanced Science, Illumina. "This early access technology is an important step toward helping researchers explore those challenging settings with greater sensitivity and generate evidence that can advance MRD research."

The new duplex sequencing technology expands the Illumina MRD research portfolio by adding an ultra-accurate option for ctDNA monitoring when greater sensitivity is needed. It complements Illumina WGS Oncology Prep, which supports both tumor fingerprinting and longitudinal ctDNA monitoring in a standardized whole-genome workflow. Announced earlier this year, WGS Oncology Prep is also available through early access.

NYU Langone Health is an early access user of the new technology, applying the approach to MRD research. "MRD research is moving fast, and new tools are making it possible to bring ultrasensitive, tumor-informed analysis in-house. We are excited to be part of the early access program and look forward to generating evidence with a non-bespoke approach that can help advance our understanding of disease recurrence," said Matija Snuderl, MD, director of Molecular Pathology at NYU Langone Health.

Kits for the early access program are expected to ship in the first quarter of 2027. The research-use-only workflow supports 5-10 ng of cfDNA input and combines NovaSeq X sequencing with duplex chemistry to deliver quality scores above Q65 for exceptionally high sequencing accuracy. DRAGEN bioinformatics generates duplex consensus reads, optimizes quality scores and interrogates thousands of tumor-specific variants across the genome, combining evidence from the few that may be present in plasma. In representative studies, the workflow demonstrated reproducible detection of ctDNA at 2.5 parts per million (ppm) levels.

Duplex sequencing confirms each base call using both complementary strands of the original DNA molecule. Observing the same change on both strands increases confidence that the finding is biological rather than an error introduced during library preparation or sequencing. Detection at low single-digit ppm levels means identifying only a few ctDNA fragments among 1 million total DNA fragments.

Illumina is advancing MRD research with scalable solutions designed for local implementation in laboratories around the world. Unlike approaches that require a custom-built panel for each sample, Illumina's WGS-based MRD research workflows use a standardized process from library preparation through DRAGEN analysis, helping simplify laboratory operations while delivering a turnaround time of less than five days. The approach allows researchers to generate and publish their data, helping to accelerate discovery and advance the field of MRD research.

Learn more about the Illumina WGS MRD research portfolio

Learn more about Illumina duplex sequencing technology

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) challenges inherent in developing and launching the new duplex sequencing workflow, including our ability to meet the expected timing for shipment of early access kits; (ii) our ability to manufacture robust instrumentation and consumables and develop reliable software solutions; and (iii) 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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