



NEWS RELEASE

Haystack MRD® Demonstrates Robust Clinical Performance in Specimen Cohort from the Landmark DYNAMIC Colorectal Cancer Trials

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Test showed 100% specificity, with no false-positive results in the cohort, at both 3- and 5-year follow-up, and sensitivity of 100% and 83.3%, respectively, for predicting disease recurrence

SECAUCUS, N.J., Oct. 1, 2026 /PRNewswire/ -- A **new study** published in The Journal of Molecular Diagnostics showed that the Haystack MRD® test is highly accurate at detecting residual and recurrent disease, demonstrating clinical performance in specimens from the landmark DYNAMIC colorectal cancer trial series. The study also validated the test's analytical performance across 23 solid tumor types. Provided by Quest Diagnostics (NYSE: DGX), **Haystack MRD** is an ultrasensitive circulating tumor DNA (ctDNA) liquid biopsy test for identifying residual or recurrent disease in patients with solid tumor cancers.

The study evaluated the clinical performance of the commercially available Haystack MRD test by retrospectively testing residual specimens from patients enrolled in the DYNAMIC and DYNAMIC-III trials, which evaluated the use of ctDNA-based MRD results (generated with an earlier version of the Haystack MRD technology) to guide chemotherapy decisions in stage II and III colorectal cancer. In this cohort, Haystack MRD results were highly associated with recurrence, demonstrating 100% sensitivity and 100% specificity at 3-year follow-up and 83.3% sensitivity and 100% specificity at 5-year follow-up. Haystack MRD also substantially outperformed carcinoembryonic antigen (CEA), a standard blood-based biomarker, detecting recurrence with 88.9% sensitivity versus 11.1% for CEA (median follow-up 60 months).

Scientists from Quest and Haystack Oncology conducted the study together with investigators from the two institutions that led the DYNAMIC trials: The Walter and Eliza Hall Institute of Medical Research and the Peter MacCallum Cancer Center in Melbourne, Australia.

"The DYNAMIC trial demonstrated the potential for ctDNA to guide more individualized treatment decisions in stage II colon cancer but realizing that potential depends on a highly sensitive assay that can reliably detect the extremely small amounts of tumor DNA that may remain after treatment, while maintaining high specificity," said Professor Jeanne Tie,* a medical oncologist at Peter MacCallum Cancer Centre and lead investigator for the DYNAMIC trial series. "This study helps bridge the gap between clinical research and real-world patient care."

In other key findings, Haystack MRD:

- Demonstrated ultrasensitive detection of residual disease, with a 95% limit of detection (LoD95) of 0.063 mean ctDNA molecules per milliliter (mL) of plasma. Earlier validation established an LoD95 of 6 parts per million (PPM), a metric commonly reported for tumor-informed MRD assays¹.
- Achieved sub-PPM detection of 0.8 PPM, and as low as 0.2 PPM in some samples, with no false positives in cancer-free controls using an investigational whole-genome version of the test. This whole-genome version is currently only available to clinical investigators and biopharma partners while the commercial test uses whole-exome sequencing.
- Established a limit of quantitation (LOQ) suitable for response monitoring of 0.25 mean ctDNA molecules per mL. Establishing the LOQ allows a change in a patient's ctDNA level between serial tests to be interpreted as a real change in tumor burden rather than assay variability.
- Demonstrated analytical performance across the complete testing process, starting from plasma collection and including cell free (cf) DNA extraction, rather than starting with already extracted cfDNA. As a result, analytical performance can be directly translated to clinical performance, versus assay validations that begin with extracted cfDNA and do not account for extraction variability.

"To our knowledge, this is the first time that the full ctDNA MRD testing process, starting from plasma collection and including cfDNA extraction, has been characterized for the limit of detection (at 95%) and quantitative analytical performance," said study co-author Dan Edelstein, Vice President and General Manager, Haystack Oncology. "The precise quantitative measurements demonstrated in this validation provide confidence that the Haystack MRD test accurately measures changes in ctDNA levels over time and can be used for serial ctDNA monitoring during and after treatment. With these insights, clinicians can understand the degree of change in ctDNA levels related to tumor biology in an individual patient, supporting earlier evaluation of treatment response and detection of molecular progression or recurrence."

In addition, the study examined a real-world clinical cohort from an Early Experience program in which Haystack MRD detected ctDNA across 27 solid tumor types, including at ultra-low concentrations, with 42% of positive results below 0.5 mean ctDNA molecules/mL.

The new study adds to the growing body of evidence supporting the clinical value of Haystack MRD, following two studies published in The New England Journal of Medicine. Published in 2022, **DYNAMIC** was the first prospective, interventional study to demonstrate the clinical utility of ctDNA-based MRD testing to reduce the use of chemotherapy in stage II colon cancer without compromising recurrence-free survival. In 2025, a **study** on response to immunotherapy in mismatch repair-deficient cancers found that the Haystack MRD test was a "reliable liquid biopsy surrogate" that identified clinical complete response at a median of 1.4 months, compared with more than 6 months using imaging.

*Dr. Tie has served as an advisor and consultant for Haystack Oncology.

About Quest Diagnostics

Quest Diagnostics works across healthcare to create a healthier world, one life at a time. We connect people, from clinicians to consumers, with laboratory insights that illuminate a path to better health. With a focus on delivering smarter, simpler testing, we help reveal new avenues to identify and treat disease, empower healthy behaviors and improve healthcare management. Quest Diagnostics serves half the physicians and hospitals in the United States and one in three American adults each year, and our nearly 60,000 employees work together to deliver diagnostic insights that inspire actions to transform lives. www.QuestDiagnostics.com

About Haystack Oncology

Haystack Oncology represents the culmination of over 20 years of collaboration to advance technical and clinical development in liquid biopsy technologies by cancer genomics pioneers at Johns Hopkins School of Medicine. The company, a wholly owned subsidiary of Quest Diagnostics, developed Haystack MRD, a tumor-informed, next-generation MRD test that detects ultralow levels of ctDNA to uncover residual or recurrent disease with exceptional sensitivity and specificity. Haystack Oncology works with biopharmaceutical companies to accelerate and inform clinical development programs and advance important therapeutics to global markets, from early phase clinical development to companion diagnostics. Haystack MRD was developed and validated in a CLIA-certified laboratory and is available for commercial use as a lab-developed test (LDT) by Quest Diagnostics. The FDA granted Haystack MRD Dx Breakthrough Device Designation in 2025 for use in Stage II colorectal cancer. Haystack MRD is also available for clinical trials as an investigational device by Haystack Oncology in laboratories located in Baltimore, Maryland; Hamburg, Germany; and Helsinki, Finland. Haystack MRD is now authorized for patient access in all 50 U.S. states. www.haystackmrd.com

Prathapam R, Champion K, Blakely K, et al. Analytical validation of the Haystack MRD assay for the detection of extremely low ctDNA in solid tumor patients. Poster presented at: Association for Molecular Pathology 2024 Annual Meeting and Expo; November 19, 2024; Vancouver, BC, Canada. doi:10.1016/S1525-1578(24)00232-0

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