NEWS RELEASE

Quest Diagnostics Receives New York State Approval for Haystack MRD®, Broadening Patient Access to ctDNA Minimal Residual Disease Testing

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Achieving the rigorous laboratory standard broadens access for providers and patients in New York; applies to use of Haystack MRD for patients with solid tumor cancers

SECAUCUS, N.J., June 24, 2026 /PRNewswire/ -- Quest Diagnostics® (NYSE: DGX), a leading provider of diagnostic information services, today announced that the New York State Department of Health's (NYSDOH) Clinical Laboratory Evaluation Program (CLEP) has approved the company's Haystack MRD® test, a circulating tumor DNA (ctDNA) liquid biopsy test, for use in identifying residual or recurring disease in patients with a range of solid tumor cancers.

New York maintains a highly rigorous clinical laboratory oversight program, requiring formal technical review and approval of laboratory developed tests before they may be offered to patients in the state. With this approval, Haystack MRD is now authorized for patient testing in all 50 U.S. states. The test was developed under CLIA regulations and has been available for clinician ordering since late 2024 in 49 states and the District of Columbia.

"This approval represents the culmination of our many years of hard work and commitment to delivering a highly accurate test that can meaningfully improve patient care," said Dan Edelstein, Vice President and General Manager for Haystack Oncology, a Quest Diagnostics company. "Haystack MRD was designed to give oncologists the confidence to detect residual disease earlier, catch recurrence before it becomes clinically apparent, and help identify response to treatment. New York's approval is another proof point for Haystack MRD's quality and technical sophistication, and we look forward to extending access to this important innovation for clinicians and patients in the state."

In addition, Haystack MRD's clinical utility has been demonstrated in rigorous investigational settings, including the landmark study of non-operative management of patients with locally advanced mismatch repair–deficient (dMMR) solid tumors, which was led by Dr. Andrea Cercek and colleagues at Memorial Sloan Kettering Cancer Center and published in The New England Journal of Medicine in May 2025. In that study, ctDNA testing, using Haystack MRD, was found to be a "reliable liquid biopsy surrogate" that identified clinical complete response at a median of 1.4 months, compared to more than 6 months using imaging methods.

"In our study of non-operative management for dMMR solid tumors, the use of MRD testing provided additional molecular information that complemented traditional assessments such as imaging and endoscopy," said Dr. Cercek, Medical Oncologist, Memorial Sloan Kettering Cancer Center. "For patients who may avoid surgery, having multiple tools to evaluate treatment response and monitor for recurrence is important. These findings highlight the crucial role of MRD testing in informing patient management and underscore the need for continued study as these approaches are integrated into clinical practice."

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 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. **www.haystackmrd.com**

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 57,000 employees work together to deliver diagnostic insights that inspire actions to transform lives. **www.QuestDiagnostics.com**

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