GeneDx Granted FDA Breakthrough Device Designation for its ExomeDx™ and GenomeDx™ Testing

October 20, 2025

Designation highlights GeneDx innovation in clinical whole genome and whole exome testing and accelerates the pathway for FDA authorization of these novel diagnostic tests

GAITHERSBURG, Md.--(BUSINESS WIRE)--Oct. 20, 2025-- GeneDx (Nasdaq: WGS), a leader in delivering improved health outcomes through genomic insights, today announced that the U.S. Food and Drug Administration (FDA) has granted Breakthrough Device Designation for its whole genome and exome tests associated with causes of life-threatening diseases or genetic disorders to aid in diagnosis of symptomatic patients.

With more than 2.5 million genetic tests performed in its CLIA certified, CAP accredited clinical laboratory, GeneDx continues to advance clinical genomic testing for rare diseases. The GeneDx ExomeDx covers the protein-coding regions, where most disease-causing variants occur, while GenomeDx sequences the entire genome to detect structural and non-coding variants often missed by other genetic testing methods like targeted panels and chromosomal microarray.

“Diagnosis informed by an individual’s genetics rather than symptoms alone can lead to improved clinical outcomes and help eliminate the typically years-long ‘diagnostic odyssey’ faced by these patients and families,” said Mimi Lee, MD, PhD, Chief Precision Medicine Officer at GeneDx. “The FDA Breakthrough Device Designation for our ExomeDx and GenomeDx tests underscores what clinical practice has shown for years, that comprehensive genomic testing should be the starting point – not the last resort – for patients with rare diseases and unexplained symptoms.”

GeneDx’s whole genome and whole exome tests are powered by GeneDx Infinity™ – the largest and most diverse rare-disease dataset, with nearly one million sequenced exomes and genomes and over 7 million phenotypic datapoints – and use next generation sequencing technology to deliver fast, reliable results across all populations.

"By combining the industry's largest and most diverse rare-disease dataset with advanced AI and deep clinical expertise, GeneDx is positioned to help clinicians deliver faster, more reliable diagnoses for families who have waited far too long for answers,” said Katherine Stueland, President and Chief Executive Officer at GeneDx.

FDA Breakthrough Device Designation is reserved for technologies that have demonstrated the potential to provide more effective diagnosis or treatment for life-threatening or irreversibly debilitating diseases. The designation provides GeneDx with an expedited pathway for FDA review – including prioritized feedback and closer collaboration with the agency – designed to accelerate the availability of safe and effective innovative diagnostic devices for patients in all 50 states.

“As a trusted partner across the healthcare ecosystem, working collaboratively with clinicians, patients, biopharma – and now with FDA – the Breakthrough designation is another milestone advancing our shared mission of making precision medicine the standard of care for all,” added Stueland.

About GeneDx

GeneDx (Nasdaq: WGS) is the global leader in rare disease diagnosis, transforming the way medicine is practiced by making genomics the starting point for health, not the last resort. We bring together unmatched clinical expertise, advanced technology, and the power of GeneDx Infinity™ – the largest, rare disease dataset – built over 25 years from millions of genomic tests and deep clinical insights. This unparalleled foundation powers our clinical genome and exome tests, giving clinicians the highest likelihood of delivering a timely, accurate diagnosis. GeneDx is shaping the future of healthcare by moving the standard of care from sick care to proactive healthcare. While our roots are in rare disease diagnosis, our commitment extends beyond – growing with the families we serve – as a trusted partner at every stage of life. For more information, visit genedx.com and connect with us on LinkedIn, Facebook, and Instagram.

Forward Looking Statements

This press release may contain “forward-looking statements” within the meaning of Section 21E of the Securities Exchange Act of 1934, as amended, and the U.S. Private Securities Litigation Reform Act of 1995. 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. Many factors could cause actual future events to differ materially from the forward-looking statements in this press release, including but not limited to: (i) our ability to implement plans to accelerate and unlock the full potential of precision medicine, (ii) our ability to secure future FDA clearance or approval; (iii) the risk of downturns and a

changing regulatory landscape in the highly competitive healthcare industry, (iv) the size and growth of the market in which we operate, (v) our ability to pursue our new strategic direction. The foregoing list of factors is not exhaustive. A further list and description of risks, uncertainties and other matters can be found in the “Risk Factors” section of our Annual Report on Form 10-K for the fiscal year ended December 31, 2024 and our Quarterly Reports on Form 10-Q for the fiscal quarters ended March 31, 2025 and June 30, 2025, and other documents filed by us from time to time with the SEC. These filings identify and address other important risks and uncertainties that could cause actual events and results to differ materially from those contained in the forward-looking statements. Forward-looking statements speak only as of the date they are made. Readers are cautioned not to put undue reliance on forward-looking statements, and we assume no obligation and do not intend to update or revise these forward-looking statements, whether as a result of new information, future events, or otherwise. We do not give any assurance that we will achieve our expectations.

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Investor Relations:
Investors@GeneDx.com

Media:
Press@GeneDx.com

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