



GRAIL and Quest Diagnostics Provide GRAIL's Galleri® Multi-Cancer Early Detection (MCED) Test Through the Quest Diagnostics Test Ordering System

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GRAIL's Galleri Test Now Directly Available to Physicians in the U.S. Through Collaboration With Quest Diagnostics, Delivering a More Streamlined Provider and Patient Experience

MENLO PARK, Calif. and SECAUCUS, N.J., Feb. 12, 2025 /PRNewswire/ -- GRAIL, Inc. (Nasdaq: GRAL), a healthcare company whose mission is to detect cancer early when it can be cured, and Quest Diagnostics (NYSE: DGX), a leading provider of diagnostic information services, today announced the initial phase of a program to improve provider access to GRAIL's Galleri® multi-cancer early detection (MCED) test. Providers can now order the Galleri test directly from GRAIL through the Quest Diagnostics connectivity system. The Quest Diagnostics connectivity system enables providers in the United States to order and receive reports of laboratory tests electronically through Quest's Quantum laboratory portal and more than 900 electronic health record (EHR) systems. More than 500,000 providers used the Quest connectivity system last year.



The integration will help streamline the process of ordering the Galleri test for physicians. It will also increase availability by allowing patients access to the test at any of Quest's approximately 7,400 patient access points nationwide. Patients with a test order from their physician can now go directly to Quest without needing to bring a Galleri test kit to the blood draw appointment.

"Quest Diagnostics and GRAIL share a commitment to improving access to cancer screening and have worked productively together to enable patient access to GRAIL's Galleri test via Quest's phlebotomy network since 2021," said Mark Gardner, Senior Vice President, Molecular Genomics and Oncology for Quest Diagnostics. "Integrating GRAIL's Galleri test into the Quest connectivity system is the next step in this collaboration. We expect it to increase patient access by giving Quest's provider clients the ability to seamlessly order the test through Quest, same as they do for other blood work. This collaboration brings to life the tremendous value of Quest's ability to scale diagnostic innovation to make it accessible for all."

Cancers growing in the body shed DNA into the bloodstream. These DNA fragments act like a unique "fingerprint" of cancer. With a single blood draw, the Galleri test screens for the "fingerprint" of many of the deadliest cancers before they become symptomatic, including those with no recommended screening tests today. It can also provide doctors with information on the cancer's origin to help predict the tissue type or organ associated with the cancer signal. The Galleri test is prescription only, recommended for adults with an elevated risk for cancer, such as those age 50 or older, and is to be used in addition to recommended cancer screenings.

"We know every minute counts for busy providers, their staff and their patients, which is why we're so pleased to work with Quest to offer a seamless experience that fits into providers' existing ordering process," said Josh Ofman, MD, MSHS, President at GRAIL. "While today there are recommended screenings for five cancers, nearly 70% of deaths are caused by cancers with no recommended screening test. We believe this integration will help to make it easier to incorporate the Galleri test into routine exams to help screen for cancer before it becomes symptomatic when outcomes may be improved."

About Quest Diagnostics

Quest Diagnostics works across the healthcare ecosystem to create a healthier world, one life at a time. We provide diagnostic insights from the results of our laboratory testing to empower people, physicians and organizations to take action to improve health outcomes. Derived from one of the world's largest databases of de-identifiable clinical lab results, Quest's diagnostic insights reveal new avenues to identify and treat disease, inspire healthy behaviors and improve healthcare management. Quest Diagnostics annually serves one in three adult Americans and half the physicians and hospitals in the United States, and our more than 55,000 employees understand that, in the right hands and with the right context, our diagnostic insights can inspire actions that transform lives and create a healthier world. www.QuestDiagnostics.com.

About GRAIL

GRAIL is a healthcare company whose mission is to detect cancer early, when it can be cured. GRAIL is focused on alleviating the global burden of cancer by using the power of next-generation sequencing, population-scale clinical studies, and state-of-the-art machine learning, software, and automation to detect and identify multiple deadly cancer types in earlier stages. GRAIL's targeted methylation-based platform can support the continuum of care for screening and precision oncology, including multi-cancer early detection in symptomatic patients, risk stratification, minimal residual disease detection, biomarker subtyping, treatment and recurrence monitoring. GRAIL is headquartered in Menlo Park, CA with locations in Washington, D.C., North Carolina, and the United Kingdom.

For more information, visit grail.com.

About Galleri®

The Galleri multi-cancer early detection test is a proactive tool to screen for cancer. With a simple blood draw, the Galleri test can identify DNA shed by cancer cells, which can act as a unique "fingerprint" of cancer, to help screen for some of the deadliest cancers that don't have recommended screening today, such as pancreatic, esophageal, ovarian, liver, and others.* The Galleri test can be used to screen for cancer before a person becomes symptomatic, when cancer may be more easily treated and potentially curable. The Galleri test can indicate the origin of the cancer, giving healthcare providers a roadmap of where to explore further. The Galleri test requires a prescription from a licensed healthcare provider and should be used in addition to recommended cancer screenings such as mammography, colonoscopy, prostate-specific antigen (PSA) test, or cervical cancer

screening. The Galleri test is recommended for adults with an elevated risk for cancer, such as those aged 50 or older.

For more information, visit [galleri.com](https://www.galleri.com).

Sensitivity in [study](#) participants with –

Pancreas cancer: 83.7% overall (61.9% stage I, 60.0% stage II, 85.7% stage III, 95.9% stage IV). Esophagus cancer 85.0% overall (12.5% stage I, 64.7% stage II, 94.7% stage III, 100% stage IV). Ovary cancer: 83.1% overall (50.0% stage I, 80.0% stage II, 87.1% stage III, 94.7% stage IV).

Liver/bile duct cancer: 93.5% overall (100% stage I, 70.0% stage II, 100% stage III, 100% stage IV).

Important Galleri Safety Information

The Galleri test is recommended for use in adults with an elevated risk for cancer, such as those aged 50 or older. The Galleri test does not detect all cancers and should be used in addition to routine cancer screening tests recommended by a healthcare provider. Galleri is intended to detect cancer signals and predict where in the body the cancer signal is located. Use of Galleri is not recommended in individuals who are pregnant, 21 years old or younger, or undergoing active cancer treatment.

Results should be interpreted by a healthcare provider in the context of medical history, clinical signs and symptoms. A test result of No Cancer Signal Detected does not rule out cancer. A test result of Cancer Signal Detected requires confirmatory diagnostic evaluation by medically established procedures (e.g. imaging) to confirm cancer.

If cancer is not confirmed with further testing, it could mean that cancer is not present or testing was insufficient to detect cancer, including due to the cancer being located in a different part of the body. False-positive (a cancer signal detected when cancer is not present) and false-negative (a cancer signal not detected when cancer is present) test results do occur. **Rx only.**

Laboratory/Test Information

The GRAIL clinical laboratory is certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) and accredited by the College of American Pathologists. The Galleri test was developed and its performance characteristics were determined by GRAIL. The Galleri test has not been cleared or approved by the Food and Drug Administration. The GRAIL clinical laboratory is regulated under CLIA to perform high-complexity testing. The Galleri test is intended for clinical purposes.

GRAIL Forward Looking Statements

This press release contains forward-looking statements. In some cases, you can identify these statements by forward-looking words such as "aim," "anticipate," "believe," "continue," "could," "estimate," "expect," "intend," "may," "might," "plan," "potential," "predict," "should," "would," or "will," the negative of these terms, and other comparable terminology. These forward-looking statements, which are subject to risks, uncertainties, and assumptions about us, may include statements about benefits of the integration between the Quest connectivity system and Galleri.

These statements are only predictions based on GRAIL's current expectations and projections about future events and trends. There are important factors that could cause our actual results, level of activity, performance, or achievements to differ materially and adversely from those expressed or implied by the forward-looking statements, including those factors discussed under the section entitled "Risk Factors" in GRAIL's most recent Quarterly Report on Form 10-Q filed with the SEC. Moreover, GRAIL operates in a dynamic and rapidly changing environment. New risks emerge from time to time. It is not possible for GRAIL's management to predict all risks, nor can they assess the impact of all factors on GRAIL's business or the extent to which any factor, or combination of factors, may cause actual results, level of activity, performance, or achievements to differ materially and adversely from those contained in any forward-looking statements GRAIL may make.

Forward-looking statements relate to the future and, accordingly, are subject to inherent uncertainties, risks, and changes in circumstances that are difficult to predict and many of which are outside of GRAIL's control. Although GRAIL believes the expectations and projections expressed or implied by the forward-looking statements are reasonable, GRAIL cannot guarantee future results, level of activity, performance, or achievements. GRAIL's actual results and financial condition may differ materially from those indicated in the forward-looking statements. Except to the extent required by law, GRAIL undertakes no obligation to update any of these forward-looking statements after the date of this press release to conform its prior statements to actual results or revised expectations or to reflect new information or the occurrence of unanticipated events.

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