



GRAIL Presents Positive Analytical Validation Data on its Methylation-Based Post-Diagnostic Cancer Research Solution at American Association for Cancer Research (AACR) Annual Meeting 2023

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Analytical Study Results Show Targeted Methylation-Based Solution Has Strong Analytical Sensitivity, Specificity, Precision and Reliability in Many Solid Tumors

Research Adds to Data Supporting Potential of GRAIL's Methylation Platform Across the Cancer Care Continuum

MENLO PARK, Calif., April 19, 2023 — GRAIL, LLC, a healthcare company whose mission is to detect cancer early when it can be cured, today presented analytical validation data on its recently launched methylation-based post-diagnosis solution to accelerate cancer research (abstract LB297). Results of the analytical study demonstrated strong analytical sensitivity, specificity and precision of the tissue-free multi-cancer post-diagnosis research solution, which leverages GRAIL's proprietary methylation platform to evaluate cell-free DNA (cfDNA) isolated from blood. The findings were presented in a late-breaking poster session at the American Association for Cancer Research (AACR) Annual Meeting 2023 in Orlando, held April 14-19.

"These results are an important step in establishing the performance of our post-diagnostic methylation-based solution for cancer research," said Jeffrey Venstrom, MD, Chief Medical Officer at GRAIL. "Current post-diagnostic cancer detection tests often require tumor tissue and are limited by their specificity to a narrow set of cancers. With GRAIL's methylation technology, the analytical study results showed that we can detect multiple types of cancer with strong sensitivity without the need for a tissue sample. This solution is a versatile option for a range of research uses including cancer prognosis, identification of minimal residual disease and recurrence monitoring, and biomarker discovery."

The analytical study analyzed cfDNA blood samples from cancer and non-cancer donors. Analytical sensitivity was assessed in 12 different solid tumor types. Results demonstrated a robust median limit of detection (LOD95) of 0.023% based on measures of the abnormally methylated ctDNA fraction. Analytical specificity was 98.47% and overall precision across replicates was 94.6%.

GRAIL [announced](#) the availability of its state-of-the-art research use only (RUO) targeted methylation-based solution offering for biopharmaceutical companies in January 2023. Several biopharmaceutical partners leveraged early access to the RUO technology solution.

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 developing pioneering technology to detect and identify multiple deadly cancer types early. The company is using the power of next-generation sequencing, population-scale clinical studies, and state-of-the-art computer science and data science to enhance the scientific understanding of cancer biology, and to develop its multi-cancer early detection blood test. GRAIL is headquartered in Menlo Park, CA with locations in Washington, D.C., North Carolina, and the United Kingdom. GRAIL, LLC, is a subsidiary of Illumina, Inc. (NASDAQ:ILMN) currently held separate from Illumina Inc. under the terms of the Interim Measures Order of the European Commission.

For more information, visit grail.com.

Laboratory/Test Information

GRAIL's clinical laboratory is certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) and accredited by the College of American Pathologists. GRAIL's clinical laboratory is regulated under CLIA to perform high-complexity testing. The RUO test was developed, and its performance characteristics were determined by GRAIL. The RUO test is for research use only, not for diagnostic purposes. GRAIL's current product offerings have not been cleared or approved by the U.S. Food and Drug Administration.

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