



GRAIL Introduces State-of-the-Art Methylation-Based Solution to Accelerate Cancer Research in the Post-Diagnosis Setting

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Next-Generation Foundational Research Use Only (RUO) Targeted Methylation-Based Solution for Post-Diagnosis Applications and Biomarker Discovery Can be Enhanced With Custom Classifier Development

MENLO PARK, Calif., Jan. 9, 2023 – GRAIL, LLC, a healthcare company whose mission is to detect cancer early when it can be cured, today announced the availability of a state-of-the-art research use only offering for biopharmaceutical companies. The new technology solution uses GRAIL's proprietary targeted methylation platform to analyze cell-free DNA (cfDNA) isolated from peripheral blood for cancer signal interrogation. Potential research use cases include, but are not limited to, prognosis, minimal residual disease detection, and recurrence monitoring across different cancer types in research studies.

"GRAIL's unique methylation technology and bioinformatics capabilities are well suited for circulating tumor DNA analysis across the cancer continuum," said Bob Ragusa, Chief Executive Officer at GRAIL. "We are excited to further leverage our methylation platform and introduce our RUO technology solution for cancer prognosis, minimal residual disease and recurrence monitoring and biomarker discovery. The new technology solution has the versatility to be used in solid tumor research and can be customized to improve performance in specific use cases, including custom classifier development."

GRAIL's RUO technology solution estimates tumor burden based on methyl variant allele fraction (MVAf), enabling longitudinal monitoring and surveillance solutions. Data from GRAIL studies have demonstrated analytically validated performance, and robust analytical sensitivity, specificity, and precision. The blood-only liquid biopsy approach eliminates challenges with obtaining tissue samples and avoids bias due to tumor heterogeneity or tumor escape mechanisms. The low input requirements support retrospective research studies.

Several biopharmaceutical partners have leveraged early access to the RUO technology solution, which is now broadly available. For more information, please visit www.GRAIL.com.

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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 Food and Drug Administration.

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