New Paper Highlights Capability of Personal Genome Diagnostics' elio™ plasma resolve Assay to Detect Microsatellite Instability

Assay also demonstrated comprehensive detection of sequence and structural alterations encountered across solid tumors.

BALTIMORE, MD, August 11, 2021 – Personal Genome Diagnostics Inc. (PGDx) today reported the publication of a research paper in *The Oncologist,* titled "Validation of a ctDNA-based next-generation sequencing assay in a cohort of solid tumor patients: a proposed solution for decentralized plasma testing," which assessed the performance of the company's elio™ plasma resolve assay. This is the first study validating that a decentralized plasma-based next-generation sequencing (NGS) test can detect microsatellite instability (MSI) status along with the comprehensive landscape of sequence and structural alterations encountered across solid tumors.

The study, from Weill Cornell Medicine's Englander Institute for Precision Medicine, profiled DNA from matched tissue and plasma samples from 75 cancer patients and showed that elio plasma resolve detected 77% of sequence alterations, amplifications, and fusions that were found in metastatic samples compared to 45% of those alterations found in the primary tumor samples. There was 87% agreement for MSI status between elio™ plasma resolve and tumor tissue results. In 3 cases, the assay's identification of MSI-high circulating tumor DNA (ctDNA) correlated with response to immunotherapy. In addition, the PGDx kit revealed an *FGFR2* amplification that was not detected in tumor tissue from a patient with metastatic gastric cancer.

"We are elated to see that in this study, elio™ plasma resolve demonstrated the comprehensive ability to identify MSI-high DNA samples from cancer patients," said Megan Bailey, Chief Executive Officer of PGDx. "We believe these results show tremendous potential for elio™ plasma resolve and the overall benefits of cell-free DNA testing, and we are hopeful that this testing can become routine practice in the treatment of cancer."

PGDx currently offers three pan-cancer NGS kitted solutions – elio™ tissue complete, an FDA cleared kit, elio™ plasma complete, a comprehensive liquid biopsy solution, and elio™ plasma resolve, which has received FDA breakthrough device designation – that provide researchers and clinicians with the ability to identify biomarkers and profile tumors through advanced genomic sequencing within their own hospital systems and laboratories. elio™ plasma resolve is designated for research use only in the U.S. and with a CE-IVD mark in Europe.

About Personal Genome Diagnostics

Personal Genome Diagnostics (PGDx) empowers the fight against cancer by unlocking actionable information from the genome. We are committed to improving clinical insight, speed of results, and healthcare economics by delivering a portfolio of regulated tissue-based and liquid biopsy genomic products for health systems worldwide. PGDx was established by researchers from Johns Hopkins

University who are pioneers in cancer genome sequencing and liquid biopsy technologies. PGDx's elio™ Platform has enabled the development of standardized tissue-based and liquid biopsy next-generation sequencing (NGS) kits for laboratories worldwide, featuring automated bioinformatics that ensures consistent results and quality of testing. By automating the data analysis process, PGDx is enabling the scalability of precision medicine with a fast, reliable, and accurate diagnostics platform. For additional information, visit www.pgdx.com.

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