



Personal Genome Diagnostics' Expanded PlasmaSELECT™ 64 Is First Liquid Biopsy Pan-Cancer Profiling Panel to Include MSI Analyses for Immuno-Oncology

—First Liquid Biopsy Assay to Include Assessment of Microsatellite Instability Status (MSI), a Surrogate Marker for High Tumor Mutational Load, that Helps Identify Patients Most Likely to Benefit from Treatment with Immuno-Oncology Therapies such as Checkpoint Inhibitors—

—Accurately Identifies Clinically Actionable Genetic Alterations across Multiple Cancer Types from Blood or Plasma without the Need for Invasive Biopsies—

BALTIMORE, MD, March 28, 2017 – Personal Genome Diagnostics Inc. (PGDx) today announced the launch of its improved PlasmaSELECT™ 64 targeted panel for pan-cancer tumor profiling and assessment of microsatellite instability status. PlasmaSELECT 64 identifies clinically actionable and functionally important sequence mutations and structural alterations across multiple cancer types using patient blood or plasma, without the need for invasive tissue biopsies. It is the first liquid biopsy tumor profiling assay to test for microsatellite instability status (MSI), a biomarker for high tumor mutational load that helps identify cancer patients who might benefit from checkpoint inhibitors and other immuno-oncology cancer therapies. PlasmaSELECT 64 incorporates proprietary PGDx technologies and bioinformatics to identify sequence mutations with unparalleled accuracy.

“We are proud to launch the revolutionary PlasmaSELECT 64 expanded assay just six months after we introduced the most accurate, clinically actionable liquid biopsy tumor profiling assay to the market,” said Doug Ward, Chief Executive Officer of Personal Genome Diagnostics. “This update is the first liquid biopsy assay that includes MSI testing as a biomarker for high tumor mutational load, thereby providing cancer patients and their oncologists with information on whether they might be candidates for immuno-oncology therapies. The ability to generate DNA tumor profiling non-invasively using blood or plasma offers many advantages and makes genomic testing more accessible and usable. Our leadership in making MSI testing available in this format is another example of PGDx’s commitment to staying at the forefront of cancer genomic testing.”

PGDx believes that PlasmaSELECT 64 is the most clinically actionable, CLIA-validated pan-cancer plasma assay available today. The genes in PlasmaSELECT 64 were selected based on their clinical relevance and actionability. They have been shown to have biological and functional relevance to aid in making treatment decisions and include regions associated with acquired drug resistance and sensitivity. PlasmaSELECT 64 includes 15 unique biomarkers, 11 of which are associated with active clinical trials. Inclusion of MSI status as a biomarker for high mutational load makes the assay especially relevant for those patients potentially suitable for treatment with immuno-oncology therapies.

MSI status as a biomarker for mutational load is important because studies have shown that patients whose tumors have a large number of mutations, or high mutational load, are also likely to harbor neoantigens, new tumor-specific antigens that can help stimulate a robust anti-cancer immune response. These patients accordingly are more likely than those with fewer mutations to respond to treatment with immunotherapy therapies, including checkpoint inhibitors such as Keytruda® (pembrolizumab) or Opdivo® (nivolumab). Researchers are also discovering that there are subsets of patients with other types of tumors who have high mutational loads, and these patients may also be more likely to respond to immuno-oncology drugs.¹

Other approaches for determining tumor mutational load require the use of DNA from tissue biopsies, which typically are available, if at all, only at the start of treatment. Liquid biopsies using cell-free tumor DNA present in patient blood or plasma make it possible to track changes in mutational status as treatment proceeds.

PlasmaSELECT 64 encompasses single base substitutions, insertions and deletions, amplifications, and rearrangements. Test results include comprehensive clinical annotations of all reported alterations, including FDA-approved therapies, clinical trials and published literature.

The exceptional level of accuracy afforded by PlasmaSELECT 64 reflects several factors unique to PGDx. The company's proprietary DNA extraction and sample preparation methods accommodate low-abundance cell-free DNA samples. PGDx's proprietary hybrid-capture processing in combination with high-coverage, next-generation sequencing further enhance the sensitivity and accuracy of results. Its proprietary VariantDx™ computational algorithms enable discrimination of sequencing artifacts and errors from bona-fide mutations

For more information on the expanded PlasmaSELECT 64 pan-cancer assay, [click here](#).

PGDx offers a complete range of cancer genome analysis tools, including exome and targeted approaches for tissue specimens, targeted approaches for plasma samples and a variety of custom tissue and plasma-based options designed to address the specific research needs of cancer researchers and drug developers. PGDx's service offerings for researchers and testing labs are complemented by the clinical services it provides through its CLIA-certified laboratory.

1. Le et al., 2015. N. Engl. J. Med

About Personal Genome Diagnostics

Personal Genome Diagnostics (PGDx) is empowering the fight against cancer by unlocking actionable information from the genome for oncology researchers, drug developers, clinicians and patients. The expert team at PGDx draws on a deep understanding of cancer biology, extensive experience in cancer genomics and clinical oncology, and the company's distinctive technologies that precisely identify and characterize unique genomic alterations in tumors. PGDx is working toward broad patient access to its genomic technologies and products, through a CLIA-certified facility providing comprehensive genomic services, as well as a portfolio of regulated tissue-based and liquid biopsy genomic testing products for laboratories worldwide. Privately-held PGDx is headquartered in Baltimore, MD. For additional information, visit PersonalGenome.com.

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