Personal Genome Diagnostics

PERSONAL GENOME DIAGNOSTICS LAUNCHES IMMUNO*SELECT*™–R FOR IDENTIFICATION OF IMMUNOGENIC CANCER MUTATIONS TO SUPPORT IMMUNO-ONCOLOGY DRUG DEVELOPMENT

ImmunoSelect-R Combines Industry-Leading Accuracy of PGDx's CancerXome™ Whole Exome Analysis and Its Predictive Bioinformatics to Guide Selection of Tumor Antigen Therapeutic Targets and Stratify Patients Who Might Benefit from Immuno-Oncology Therapies

Exceptional Performance of PGDx's Exome Analysis Demonstrated in High Profile Immuno-Oncology Research such as Study of Genetically-Mediated Differences in PD-1 Blocker Response Being Presented at 2015 ASCO Annual Meeting

Visit Booth 24085 at ASCO to Learn More about PGDx's Broad Range of Advanced Genomic Analysis Services for New Drug R&D and Personalized Medicine

BALTIMORE, MD, May 29, 2015 – Personal Genome Diagnostics, Inc. (PGDx), a provider of advanced cancer genome analysis and testing services, today announced the launch of its Immuno*Select*™-R service designed to identify mutant neoantigens and support development of immuno-oncology cancer therapies. The new service combines the industry-leading accuracy of PGDx's CancerXome™ analysis with its proprietary bioinformatics neoantigen prediction pipeline specifically designed for immuno-oncology applications.

Neoantigens are peptides containing tumor-specific mutations that may be capable of inducing an immune response to cancer. The exquisite tumor specificity of neoantigens makes them good targets for immunotherapy. However, identification of the most immunogenic peptides requires highly accurate and comprehensive exome sequencing and tumor-specific mutation detection, as well as use of downstream approaches that filter and validate the results to identify the most promising immunotherapy candidates. PGDx's proven accuracy in exome sequencing and its associated analytic technologies for variant detection have already contributed to advances in clinical immuno-oncology. Immuno*Select*-R is intended to make these approaches more widely available to drug researchers and developers.

For example, in a 2014 National Cancer Institute proof-of-concept study published in *Science*, Tran, et al.[1], PGDx's whole exome sequencing and mutation detection were used to identify the neoantigens that were the targets for a pioneering T-cell therapy.

More recently, PGDx conducted the exome sequencing and tumor-specific mutation detection that identified key predictors of immunotherapy drug response in a study on immune checkpoint blockade being presented tomorrow at the 2015 ASCO Annual Meeting, PD-1 Blockade in Tumors with Mismatch Repair Deficiency. In the study, researchers found that colorectal cancer patients who had tumors with a mismatch repair (MMR) deficiency had a much greater therapeutic response to the programmed death 1 (PD-1) blocker, pembrolizumab, than patients who did not have the MMR deficiency. PGDx's highly sensitive and specific mutation analyses showed that cancer patients with the MMR deficiency on average had more than 20 times as many mutations in their tumors as similar patients who were not MMR deficient. This finding is consistent with other studies showing that PD-1 blockers are most effective against tumors containing many mutations. The authors conclude that MMR status can predict whether cancer patients are likely to obtain clinical benefit from PD-1 blockers such as pembrolizumab.[2] A version of this study is also being published in the New England Journal of Medicine.

Drew M. Pardoll, MD, PhD, Abeloff Professor of Oncology, Medicine, Pathology and Molecular Biology and Genetics at the Johns Hopkins University School of Medicine, commented, "This study is a reminder of how tumor-specific genetic information can be essential to optimizing cancer treatment for the individual patient, as well as for effective drug development. Tumor-specific data will be increasingly useful as promising new immuno-oncology agents come online, so the growing accessibility of sophisticated genomic analysis tools is a welcome development."

"We designed Immuno*Select* to support the strong emerging interest in immuno-oncology therapies among our cancer research clients," said Antony Newton, Chief Commercial Officer of PGDx. "PGDx was an early leader in cancer whole exome sequencing and highly sensitive and specific identification of somatic mutations. Our new service leverages that expertise and our Cancer*Xome*™ analytic platform to achieve unparalleled accuracy in detecting relevant tumor-associated mutations. In addition, we have incorporated our extensive experience in cancer genomics into a bioinformatics pipeline that prioritizes drug targets with high sensitivity and specificity. We believe there is significant opportunity in making these powerful tools available to our growing customer base for the development of immuno-oncology therapies."

The accuracy of Immuno*Select*-R is further strengthened by the extensive use of tumor/normal control DNA comparisons, ensuring exclusion of false positive germline mutations. The high incidence of false positive results in tumor-only DNA analyses was highlighted in a recent study in *Science Translational Medicine,* Jones et al.[3] conducted by PGDx in collaboration with academic researchers.

Immuno*Select* identifies true somatic mutations with 95% sensitivity and 97% PPV down to 10% mutant allele frequency. PGDx uses 100 to 1,000 times more independently-validated data points than competitors to optimize its bioinformatics pipeline, thereby reducing false positive somatic mutation calls by 50-90% over competing cancer exome analyses. The company also employs a proprietary strategy to select the best neo-antigen candidates for experimental validation.

The service can be used with either FFPE or frozen tissue. For more information about PGDx's Immuno*Select* service, visit http://main.personalgenome.com/research-services/tissue/#exome.

To learn more about PGDx's cancer genomics services, visit **Booth 24085** at the 2015 ASCO Annual Meeting in Chicago, IL, May 29–June 2, 2015. See too PGDx's posters at ASCO 2015, which include the following:

Personalized genomic analyses for cancer mutation discovery and interpretation.
Abstract No: 1529; Poster Board Number #353
J Clin Oncol 33:5s, 2015 (suppl; abstr 1529)

A non-invasive liquid biopsy approach for therapeutic stratification of lung cancer patients
Abstract No: e19082 (Publication only)
J Clin Oncol 33:5s, 2015 (suppl; abstr e19082)

A method for comprehensive genomic analysis of cell-free DNA.
Abstract No:e22070 (Publication only)
J Clin Oncol 33:5s, 2015 (suppl; abstr e22070)

A comprehensive noninvasive approach for the stratification of lung cancer patients for targeted therapies.
Abstract No: e22086 (Publication only)
J Clin Oncol 33:5s, 2015 (suppl; abstr e22086)

[1] Cancer Immunotherapy Based on Mutation-Specific CD4+ T Cells in a Patient with Epithelial Cancer, Eric Tran, Simon Turcotte, Alena Gros, Paul F. Robbins, Yong-Chen Lu, Mark E. Dudley, John R. Wunderlich, Robert P. Somerville, Katherine Hogan, Christian S. Hinrichs,Maria R. Parkhurst, James C. Yang, Steven A. Rosenberg, *Science*, 9 May 2014, Vol 344; 642-645

[2] PD-1 blockade in tumors with mismatch repair deficiency, Dung T. Le, Jennifer N. Uram, Hao Wang, Bjarne Bartlett, Holly Kemberling, Aleksandra Eyring, Andrew Skora, Nilofer Saba Azad, Daniel A. Laheru, Ross C. Donehower, Brandon Luber, Todd S. Crocenzi, George A. Fisher, Steve M Duffy, James J. Lee, Minori Koshiji, James R. Eshleman, Robert A Anders, Bert Vogelstein, Luis A. Diaz; J Clin Oncol 33, 2015 (suppl; abstr LBA100)

[3] Personalized genomic analyses for cancer mutation discovery and interpretation. S. Jones, V. Anagnostou, K. Lytle, S. Parpart-Li, M. Nesselbush, D. R. Riley, M. Shukla, B. Chesnick, M. Kadan, E. Papp, K. G. Galens, D. Murphy, T. Zhang, L. Kann, M. Sausen, S. V. Angiuoli, L. A. Diaz Jr., V. E. Velculescu, Science Translational Medicine 7, 283ra53 (2015).

About Personal Genome Diagnostics
Personal Genome Diagnostics (PGDx) provides advanced cancer genome analyses to oncology researchers, drug developers, clinicians and patients. The company uses advanced genomic methods and its deep expertise in cancer biology to identify and characterize the unique genomic alterations in tumors. PGDx's proprietary methods for genome sequencing and analysis are complemented by its extensive experience in cancer genomics and clinical oncology. PGDx's CLIA-certified facility provides personalized cancer genome analyses to patients and their physicians. For more information, visit personalgenome.com.

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