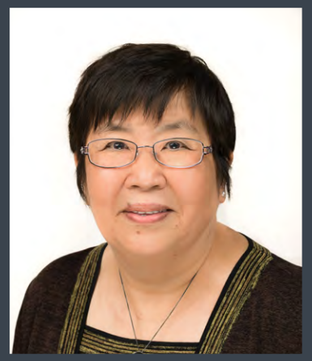


Veteran Regulatory Expert Dr. Maria Chan Will Lead PGDx Regulatory Strategy

PGDx is excited to welcome Dr. Maria Chan as Vice President for Regulatory Strategy. She is a lifelong scientist who will play a major role in shaping the company's regulatory strategy and oversee all regulatory activities.

Joining the PGDx team is the latest step in Dr. Chan's remarkable scientific career, which has been a whole lifetime in the making.

From her very early years growing up in Hong Kong, Maria was intensely interested in science and medicine. As a young schoolgirl, her initial scientific forays were biology based – dissecting the salivary system of cockroaches, and dissecting dogfish. To the great surprise, and subsequent support, of her mother, Maria stored her dogfish specimens in the family refrigerator.

From such humble, formative beginnings are world-class scientific careers launched. Dr. Chan received her PhD in immunology from the State University of New York at Buffalo. She completed her post-doctoral training in immunogenetics at Johns Hopkins. For the past 15 years she has been a reviewer and diagnostics division director at the U.S. Food and Drug Administration.

"We are thrilled to add a leader with the vast regulatory expertise and deep insights of Maria Chan heading our regulatory efforts," said Doug Ward, continued...

January 2017

Heard it Through the Pipeline

Newsletter

Your quarterly resource summarizing what's new and upcoming with our specialized approaches for cancer genome analysis and applications in research and development.

Research

ImmunoSELECT™ Demonstrates How Resistance To Checkpoint Blockade Therapy Evolves

PGDx is in the news again, this time with great news about its ImmunoSELECT technology. As reported in Cancer Discovery, a major new immuno-oncology (IO) study has confirmed the utility of ImmunoSELECT. The study demonstrated that acquired resistance to immune checkpoint inhibitor cancer drugs can develop as the landscape of somatic mutations evolves to remove the IO-targeted neoantigens.

Mark Sausen, PhD, PGDx Vice President of Research & Development, provided therapeutic context for the study and its results, "Despite the efficacy and durability of IO treatment therapies, some patients develop resistance to therapy. This study for the first time elucidates how this resistance may result from the evolving cancer genome landscape. ImmunoSELECT's comprehensive, multi-dimensional approach revealed that in patients developing therapeutic resistance, somatic mutations specifically targeted the IO therapy disappeared."

By identifying neoantigens, which are potentially immunogenic cancer mutations, ImmunoSELECT aids in the development of immuno-oncology therapies. 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, their identification requires highly accurate and comprehensive exome sequencing and tumor-specific mutation detection, as well as downstream approaches that can further enrich and categorize the results.

ImmunoSELECT identifies neoantigens by combining the industry-leading accuracy of PGDx's CancerXOME™ analysis with the company's proprietary predictive bioinformatics pipeline specifically designed for immuno-oncology applications.

ImmunoSELECT is one of the full range of cancer genome analysis tools offered by PGDx. These tools include exome and targeted approaches for tissue specimens and plasma samples, as well as a variety of custom tissue and plasma-based options designed to meet the specific needs of cancer researchers and drug developers.

"The study's findings illustrate the value of ImmunoSELECT's highly sensitive and specific approaches for whole-exome analyses and its multi-dimensional platform for neoantigen prediction," explained Dr. Sausen. *"The elucidation, discovery and validation of mutations that may be candidate neoantigens require a highly accurate mutation detection approach combined with integrated interpretation methods. ImmunoSELECT's demonstrated ability to evaluate the effects of cancer therapy on the neoantigen landscape provides researchers with the detailed information they need to develop cancer immunotherapies and guide treatment options."*

A pan-cancer assay to accurately identify tumor-specific alterations

With this knowledge, laboratories can prepare better samples to get the most out of their studies and optimize patient care.

Product Launch

CancerSELECT™ 125

PGDx is thrilled to announce the release of the new CLIA-certified CancerSELECT 125 assay for tissue. This assay identifies new clinically relevant genes and is a new and improved fusion of past CancerSELECT panels – CancerSELECT™ 88 and CancerSELECT™ 203. In contrast with past CancerSELECT panels, CancerSELECT 125 is intended to be used for clinical diagnostics, although it may be utilized for research purposes as well.

The panel of 125 genes was carefully selected based on clinical actionability, and it is equipped with groundbreaking microsatellite instability (MSI) technology that is unique to PGDx. According to recent scientific research led by PGDx founder Luis Diaz, MSI is an important biomarker that predicts response to cancer immunotherapy; the greater the mutation load caused by mismatched repair-deficient proteins, the greater the patient's response to PD-1 checkpoint inhibitors such as pembrolizumab.

This is also the only tissue panel offered with a tumor-normal option, which filters out hereditary germline mutations to increase the accuracy of the assay. Because of this, CancerSELECT 125 achieves market-leading accuracy able to sequence tumors down to a 2% mutant allele frequency with >99% sensitivity and >99.9999% specificity. Additionally, the technology utilizes patented PARE, digital karyotyping, and VariantDx, and the panel identifies structural alterations including amplifications and rearrangements. With its very high accuracy in identifying tumor-specific alterations, CancerSELECT 125 will better inform treatment decisions in the clinic and lead to better patient outcomes.

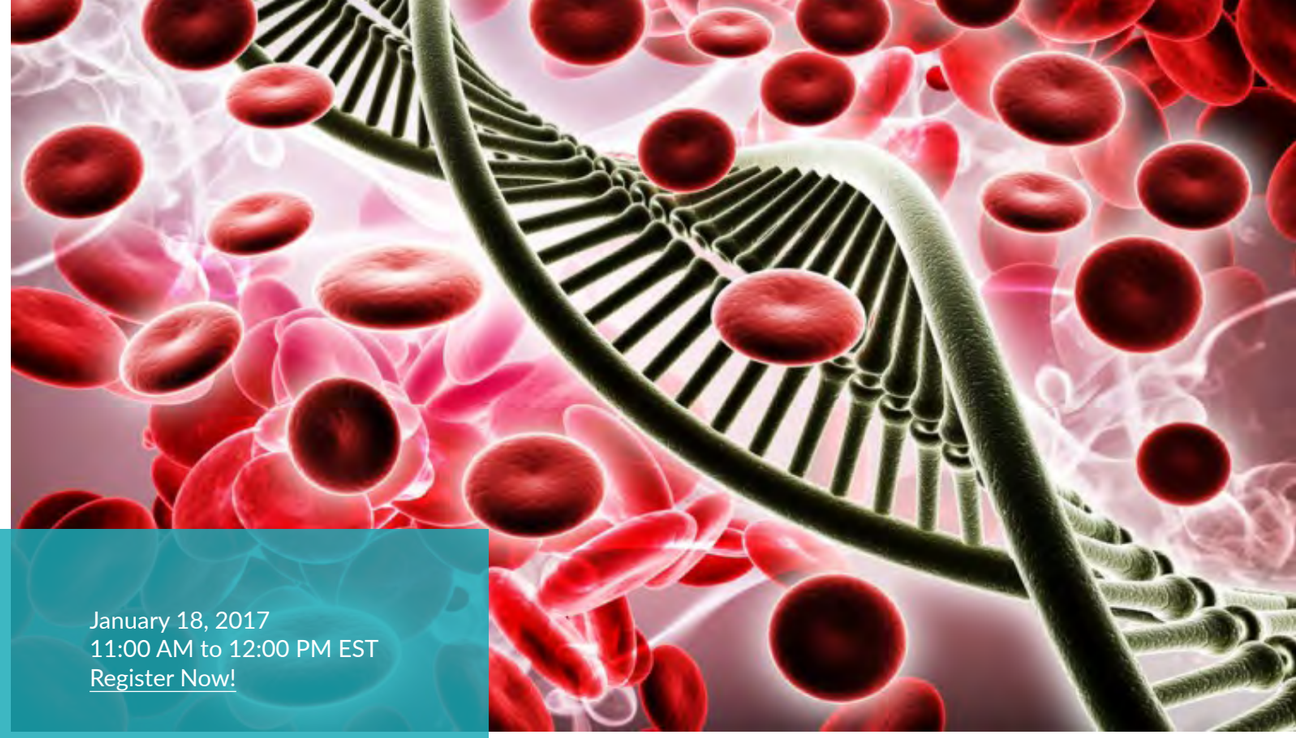
Research

Optimized Plasma Collection Procedures for Liquid Biopsy Analyses in Cancer

PGDx scientist Dr. Sonya Parpart-Li recently concluded an investigation of techniques for the preparation and preservation of blood after collection. Her study was conducted in response to the rise of ctDNA and the need for diagnostics companies and academic centers to prepare the most robust liquid biopsy assay. The study also reflects the recognition that sample preparation is a key to maximizing ctDNA potential.

Working with fellow PGDx scientists and researchers at the Sidney Kimmel Comprehensive Cancer Center at Johns Hopkins, Sonya compared EDTA and Streck to determine how long samples stay effectively preserved using each method. The study found there is no difference in the preservation of plasma in EDTA and Streck tubes for the first 24 hours. However, after 24 hours, samples in EDTA tubes tend to degrade slowly and ctDNA extraction becomes less effective.

These results may help us better understand how to prepare plasma from blood, and could enhance the robustness of liquid biopsy technology. With this knowledge, laboratories can prepare better samples to get the most out of their studies and optimize patient care.



January 18, 2017
11:00 AM to 12:00 PM EST
Register Now!

Webinar

Evaluation of Liquid Biopsy Methods in SCLC Drug Development

Learning Objectives:

- Understand the emerging role for ctDNA profiling in the cancer care continuum and drug development
- Evaluate liquid biopsy approaches as noninvasive tools for biomarker discovery and characterization
- Discuss a study utilizing liquid biopsy tools in SCLC

On January 19th, Dr. Sunita Badola, Director of Functional Genomics at Takeda and Dr. John Simmons, Director of Translational Science & Diagnostics at PGDx will discuss the applications of ctDNA and CTC technologies in drug development applications.

Dr. Simmons will present the PGDx PlasmaSELECT™ circulating tumor DNA (ctDNA) technology which comprehensively detects genetic alterations at low allele frequencies in the circulation of cancer patients, including sequence mutations, translocations, and copy number amplifications. Both our off-the-shelf, CLIA-validated PlasmaSELECT64 assay and the option of creating customized panels will be discussed.

Dr. Badola will present the results of a single center prospective study in patients with relapsed refractory (R/R) Small Cell Lung Cancer (SCLC). SCLC is an aggressive subtype of lung cancer associated with poor survival outcomes. This study profiled both circulating tumor cells (CTCs) and ctDNA, measuring CTC counts and quantifying circulating DNAs from twelve R/R SCLC patients. CTCs and ctDNA were profiled from these patients in order to identify various genetic alterations including gene amplifications. As SCLC is rarely treated by surgery and few specimens are available for molecular characterization, there is a need for a readily available, noninvasive method to characterize biomarkers. A greater understanding of the molecular profile of SCLC is essential for development of novel targeted therapies, and resection poses an unacceptable risk to patient health and may be detrimental to patient prognosis. The results of the study suggest that CTCs and ctDNA can serve as valuable liquid biopsy tools for the genetic profiling of SCLC patients which may provide the means for the identification of prognostic or predictive biomarkers and ultimately lead to improved therapeutic outcomes and patient survival. To watch the webinar, click here to register.

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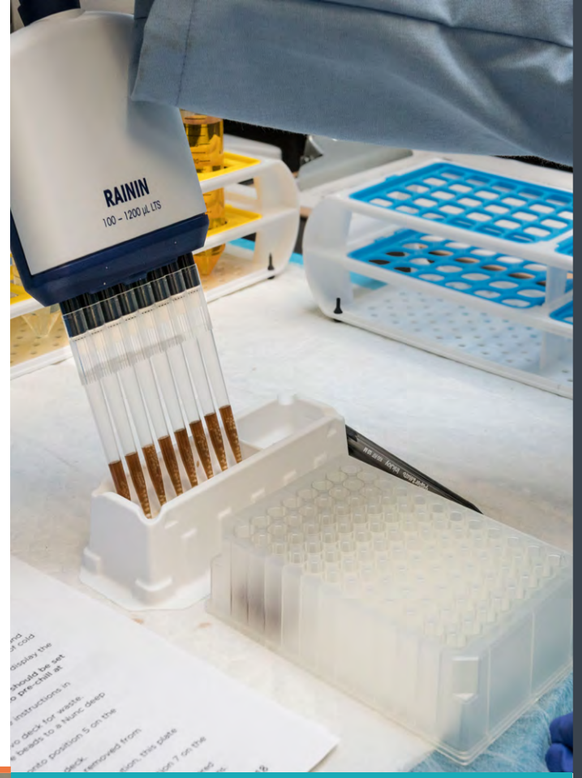
Veteran Regulatory Expert Dr. Maria Chan Will Lead PGDx Regulatory Strategy continued...

PGDx CEO. “Dr. Chan combines a strong science background and hands-on experience at the FDA, which, during her tenure, experienced a period of great technological and regulatory change. As we continue to expand the PGDx portfolio of advanced cancer genomics tests, we will look for Dr. Chan to help us navigate the evolving regulatory environment.”

“When I met the PGDx team, I was very impressed. There are great scientists here and they’re very willing to accept new ideas,” said Dr. Chan. “PGDx is a pioneer with a foundational commitment to scientific leadership in cancer genomic testing. I’m thrilled to work with the exceptional PGDx team to develop and refine our regulatory strategies as we add in vitro diagnostic tests to our growing menu of laboratory-based assays that use precision medicine to improve patient outcomes.”

For Dr. Chan, scientific success is judged by its contribution to society. So she is especially excited to have joined PGDx to help further its mission of advancing the fight against cancer.



Quality & Regulatory

Enhancing Quality Commitments through Accreditations

The PGDx team is committed to market-leading quality and works hard to ensure that patient results meet the highest level of quality assurance. As a result, PGDx is seeking two laboratory accreditations, CAP and ISO 15189, in 2017.

The Laboratory Accreditation Program (LAP) of the College of American Pathologists (CAP) is credited as the gold standard in clinical laboratory quality. CAP accreditation is voluntary and requires a peer review assessment to ensure compliance with established performance standards. PGDx anticipates full CAP accreditation in Q2 2017.

Additionally, PGDx is voluntarily seeking the globally recognized ISO 15189:2012 accreditation. Adherence to this standard is not required in the US, however, the result of adapting to systemic process review, modification, and improvement, as addressed in ISO 15189, is the reduction of laboratory errors, increased quality performance, and a greater sense of data confidence. The ISO 15189 inspection is scheduled for February 2017.

By complying to both CAP and ISO 15189 requirements, we further our commitment to quality lab results and improved patient outcomes.

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Events: At a Glance

Fluidigm IMMUNOTHERAPY WORLD

January 17-20, 2017
Hyatt Regency
Miami, Florida

REGISTER NOW!

Molecular Med TRI-CON 2017
February 19-24, 2017 | Moscone North Convention Center | San Francisco, CA

February 19-24, 2017
Moscone North Convention Center
San Francisco, California

REGISTER NOW!

NCCN National Comprehensive Cancer Network®

March 23-25, 2017
Rosen Shingle Creek
Orlando, Florida

REGISTER NOW!

Press Releases & Webinar

At a Glance

January 18, 2017

Register the PGDx Webinar: Evaluation of Liquid Biopsy Methods in SCLC Drug Development

January 4, 2017

PGDx’s ImmunoSELECT™ Technology Demonstrates How Resistance to Checkpoint Blockade Therapy in Cancer Discovery Study

December 28, 2016

Evolution of Neoantigen Landscape during Immune Checkpoint Blockade in NSCLC

December 19, 2016

PGDx Launches CancerSELECT™ 125 Test for Pan-Cancer Tumor Profiling

November 29, 2016

Veteran Regulatory Expert Maria Chan Joins Personal Genome Diagnostics

October 24, 2016

PGDx Launches RNAcomplete Allowing Co-Extraction and Analysis of RNA and DNA from a Single FFPE Tissue Sample

CLICK HERE TO SCHEDULE YOUR APPOINTMENT

January 30 - February 1, 2017
Precision LBx Summit - San Diego, CA

February 16 - 18, 2017
Genitourinary Cancers Symposium- Orlando, FL

February 21 - 22, 2017
Biomarkers Congress- Manchester, UK

February 23 - 25, 2017
Clinical Immuno-Oncology Symposium- Orlando, FL

March 20 - 24, 2017
Immuno-Oncology Summit- London, UK

March 29 - 30, 2017
World CDx Europe- London, UK