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A focus on FFPE

10-10-2019

by [Lori Lesko](#) | [Email the author](#)

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SOUTH EASTON, Mass.—Two research centers have reported “excellent results” after analyzing the Pressure Cycling Technology (PCT) platform of [Pressure BioSciences Inc. \(PBI\)](#) for processing preserved formalin-fixed paraffin-embedded (FFPE) and fresh frozen biopsy tissue samples for discovery and elucidation of cancer biomarkers, and for potential use in clinical diagnostics. These positive results were published in two journal articles in August 2019, led by independent teams of scientists in China and Australia.

The Chinese team from [Westlake University](#), a non-profit research institute in Hangzhou, China, wrote “High-throughput proteomic analysis of FFPE tissue samples facilitates tumor stratification,” published in *bioRxiv*. Westlake also purchased its first two PCT platforms in 2017 and subsequently purchased four additional PCT systems, PBI reports.

The article “Addressing the Challenges of High-Throughput Cancer Tissue Proteomics for Clinical Application” appeared in *Proteomics*, and was written by [The Australian Cancer Research Foundation \(ACRF\) International Centre for the Proteomics of Human Cancer \(ProCan\)](#), located in laboratory facilities at the Children’s Medical Research Institute (CMRI) near Sydney, Australia. ProCan bought its first PCT system in 2016 and subsequently added five more PCT platforms, according to PBI.

“There are billions of FFPE-preserved biopsy tissue samples in laboratories worldwide,” said Richard T. Schumacher, president and CEO of PBI. “Because of the in-depth clinical history over many years on such samples, they represent a potential gold mine of information for research scientists working in cancer and other human diseases and disorders. However, up to now, it has been very difficult to extract high-quality proteins from such samples. These recent publications from China and Australia described robust and reproducible PCT-based methods that allowed for the successful analysis of FFPE and other biopsy samples. This is a very exciting development.”

“Going forward, we will continue to support these and other collaborators worldwide who are working on improving PCT-based methods to better access the biomolecules hidden in FFPE and other preserved biopsy samples,” Schumacher added. “We also plan to work with companies that have existing tools that could be combined with PCT to allow for faster, higher-quality and more specific extraction of proteins, such as using lasers and other techniques.”

FFPE-preserved tissue samples are an invaluable resource for retrospective studies of disease progression and response to therapy because the disease outcome associated with the tissue and patients’ treatment history are known, Schumacher noted. He reported that current estimates are that “millions of new FFPE tissue samples processed and stored each year,” and yet analysis of samples has been an issue due to how permanent the preservation techniques are.

“Significantly, both publications cited here, together with other publications, report excellent results using the PCT sample preparation platform for comprehensive and reliable extraction and presentation of important proteins for

analysis—both from FFPE and fresh frozen tissue samples,” Schumacher remarked.

Roxana McCloskey, PBI director of marketing and sales, says, “We believe that our PCT platform is establishing itself as the method of choice for the superior extraction of potential biomarkers and their presentation for the effective proteomic analyses that will propel the growth of this huge market.”

“We expect this exciting, now proven application of our PCT platform for protein biomarker discovery in fresh frozen and FFPE biopsy samples to manifest itself in increased instrument sales starting in the second half of 2019,” McCloskey adds.

The global cancer biomarkers market, alone, is expected to exceed more than \$157 billion by 2022, according to a MarketWatch report on Jan. 8, 2019.

Regarding the *bioRxiv* article, Prof. Tiannan Guo, laboratory director at Westlake University, explained, “We developed the PCT-SWATH/DIA method of coupling pressure cycling technology for sample preparation with a high-throughput mass spectrometry workflow, to analyze FFPE tissue proteomes.”

“We believe that the vast reservoirs of historical FFPE tissue samples accumulated in biobanks worldwide offer enormous potential using our methods for biomarker discovery by leveraging the practicality and superiority of PBI’s PCT sample preparation platform for maximizing the diversity and abundance of results from FFPE samples, followed by mass spectrometry analysis in the PCT-SWATH/DIA workflow.”

Prof. Phil Robinson, co-director of ProCan, stated, “The key to clinical application of tissue-based proteomics is to adapt to the practical requirements of clinical workflow. Our results from FFPE tissues following PCT sample preparation are consistent with other reports showing that high-quality data can be generated, and that the scale and scope of quantifiable proteins is comparable to that obtained from fresh frozen tissues.”

After samples are collected, “tissue lysis and digestion protocols must be rapid, efficient, reproducible and broadly applicable to tissues of different kinds and from different source laboratories,” Robinson adds. “In addition, the methodology should be adaptable for integration of robotics to facilitate high throughput where possible.”

In the *Proteomics* paper, ProCan researchers wrote, “The cancer tissue proteome has enormous potential as a source of novel predictive biomarkers in oncology. Progress in the development of mass spectrometry (MS)-based tissue proteomics now presents an opportunity to exploit this by applying the strategies of comprehensive molecular profiling and big-data analytics that are refined in other fields’ omics research ... There are many challenges to overcome before the potential of proteomics in oncology is realized. Chief among these is to establish a knowledge-base of sufficient size and scope to address complex clinical issues.”

To date, “MS-based tissue proteomics has been a relatively low-throughput technology and most cohorts in published cancer studies are small,” the authors added. “To enable robust discovery, a large number of cancer samples must be analyzed in a consistent, or at least a comparable, way. The corollary is that a commitment is needed to develop core processes, methods and infrastructure that can operate at scale, and without compromise to the central tenets of analytical validity and clinical utility which are critical for clinical application.”

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