BME Seminar

Friday, October 28th, 2022

BUSN 211

12:00 noon - 1:00 pm

“Precision Tools for Cancer Biomarker Assay Optimization and Quality Control”

Presented by: Dr. Regan Fulton

Abstract: Cancer biomarker testing is critical for diagnosis, prognosis, and guiding patient therapy. Biomarker testing in the pathology laboratory is most commonly performed using immunohistochemistry (IHC). IHC remains a semi-quantitative method and it is challenging to validate and control these assays. Consequently, the inter-laboratory reproducibility of IHC is poor and there can be profound therapeutic consequences for patients. We have developed novel methods and instruments to assess laboratory proficiency in IHC, as well as to provide products for assay validation and daily quality control. This talk will focus on our experience trying to overcome the inherent challenges of producing control and calibration material for IHC and lead to a discussion of emerging concepts and future directions for addressing this urgent need.

Biography: Dr. Fulton’s undergraduate education was at the University of Chicago. His completed his MD and PhD training at the University of Minnesota and completed postgraduate training in Anatomic Pathology including two fellowships (Surgical Pathology and Immunodiagnosis) at Stanford University. He is board-certified in Anatomic Pathology. Dr. Fulton joined Kaiser Permanente Medical Center in San Francisco, CA in 2001, and served in the roles of Chief of Pathology, Medical Director of the Regional Immunohistochemistry Laboratory and Consultation Service, CLIA Laboratory Director, and Assistant Chief of the Medical Center Quality Department.

In his outside professional involvements, he served on the College of American Pathologists IHC Committee from 2009 to 2014 and continues to serve the on the Workgroup for IHC Validation Guidelines. Together with Dr. Allen Gown and Dr. Jeffrey Goldsmith, he created an online course providing quality management training for IHC laboratory medical directors. Also, with Dr. Allen Gown and Dr. Jason Hornick, he developed a two-day course on Diagnostic Immunohistochemistry offered by the American Society of Clinical Pathology in 2014 and 2015.

Dr. Fulton has served on the scientific advisory boards for several pharma and biotechnology companies and he is a member of the editorial board of the Journal of Applied Immunohistochemistry and Molecular Morphology. He was founding director of the International Society of Immunohistochemistry and Molecular Morphology and served as the original Secretary/Treasurer.

Dr. Fulton joined PhenoPath Laboratories, Seattle, WA in September 2013 and continued there until December 2019. He served as an attending pathologist and Director of Contract Research. His clinical service included expert consultations in solid tumor pathology and the development and validation of new assays. His contract research activities included method development in IHC, RNA-ISH, immunofluorescence, multiplex IHC assays, and image analysis, in addition to extensive assay interpretation.

He holds patents for novel methods and apparatus for tissue (TMA) and cell culture microarray (CMA) manufacturing and is the co-founder of Array Science, LLC. Now, as a private consultant, he continues to support all phases of clinical trials, including FDA submissions for companion diagnostic IHC assays. His research interests are primarily focused on developing standardized reference material for immunohistochemical assays, for initial optimization, assay validation and ongoing performance monitoring. These research efforts have focused on predictive biomarkers for targeted cancer therapy, including PD-L1, HER2, and Ki-67.