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Serum and tissue biomarkers for biospecimen integrity

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Abstract

High quality biospecimens with appropriate clinical annotation are critical in the era of biomarker discovery in personalized medicine. Several pre-analytical variables affect human biospecimen integrity for biomarker research in cancer. This situation is applicable to a variety of biospecimens including plasma/serum and fixed cancer tissues used for biomarker analysis. The U.S. National Cancer Institute (NCI) Biorepositories and Biospecimen Research Branch (BBRB) was established in 2005 to coordinate NCI's biospecimen resource activities and address those issues that affect access to the high quality specimens for biomarker research. A Biospecimen Research Network (BRN) was established to fund research to develop additional evidence-based practices used to develop serum and tissue biomarkers for human biospecimen integrity. We describe the development of assays and identification of biomarkers that may be used as sentinel markers of plasma/tissue stability in biobanks using mass-spectroscopy proteomics, circulating miRNA and immunostaining of FFPE tissues (AQUA technology). The first NCI/BBRB-funded project involves the identification of protein biomarkers using mass-spectrometry and illumina arrays in serum obtained from breast cancer and matched normal subjects, to develop guidelines for blood collection and storage. A second project studied effects of pre-analytical variables on circulating miRNA and identification and validation of new and improved housekeeping miRNA and biomarkers associated with breast cancer. In another study, a series of biomarkers have been validated by construction of tissue microarray (TMA) from 93 breast cancer specimens with known time to fixation as a pre-analytical variable. A tissue quality index (TQI) model was generated to predict the time to fixation and tissue quality by studying a subset of biomarker proteins in breast cancer tissues using AQUA scores. This presentation will outline the progressive efforts taken by BRN, investigator-led projects to identify and validate biomarkers for human biospecimen integrity.

Biography

Lokesh Agrawal directs and leads Biospecimen Research Network (BRN)-PI-led projects on human biospecimen integrity and biomarker development by studying pre-analytical variables using proteomics and molecular approaches. His work also involves leading the collaboration with several other programs/institutions at the NCI including the office of physical sciences and oncology (OPSO) and Center for Strategic and Scientific Initiatives (CSSI). Dr. Agrawal has expertise in biomarker development including clinical laboratory science and regulatory experience to strengthen BBRB programs in biospecimen acquisition and biospecimen research. Dr. Agrawal worked most recently at MedImmune Inc., where he was a team leader on various projects involving pre-clinical/clinical biomarker assay development/validation and managed several cross functional teams across to qualify and validate clinical biomarker assays; CTC's, SNP's, vaccine immunogenicity, B and T-cell proliferation & repertoire analysis. Prior to MedImmune he worked at Rapid Pharmaceuticals, Inc., as a team leader in infectious diseases/vaccines biomarker and clinical end point assay development, qualification and validation in collaboration with contract research organizations (CRO's). Dr. Agrawal also led and directed several NIH-sponsored projects at Thomas Jefferson University and did his postdoctoral fellowship at Indiana University-Purdue University at Indianapolis (IUPUI). He earned his Ph.D. from All India Institute of Medical Sciences, India and did his M.S., and B.S. at different institutions in India. Dr Agrawal has authored and co-authored several manuscripts in high impact journals and has given/presented his work at both national and international conferences. Dr Agrawal has published extensively on antioxidant gene therapy approaches against neuroinflammation/neurodegeneration, dopaminergic neurons apoptosis, rat models of ischemia, role of caspases, metalloproteinases and VEGF. Dr Agrawal was the first one to show the Role for CCR5Delta32 protein in resistance to R5, R5X4, and X4 human immunodeficiency virus type 1 in primary CD4+ cells using recombinant Adenoviruses and has developed assays to quantify viruses in blood. Dr. Agrawal main interests include development and validation of human (both normal and cancer) biospecimen integrity markers using proteomic and molecular approaches and novel biomarkers for cancer treatment and diagnosis.