

Biomarkers and Clinical Proteomics

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The landmark completion of the human genome project and the methodological breakthrough that has taken place within proteomics and functional genomics in the last decade promise to have a major impact on clinical practice, as these developments are likely to change the way in which diseases will be diagnosed, treated, and monitored in the near future. Today, we are moving increasingly from the study of cultured cells to the analysis of freshly collected cells, tissue samples, and biofluids, and one of the main challenges we face is how best to apply these powerful novel technologies to the study of clinically relevant samples in a well defined clinical and pathological framework.

Proteomics in its clinical embodiment is poised to become an important medical discipline in the near future, as identification of novel disease biomarkers complemented by an improved understanding of the pathophysiology of disease has the potential to significantly aid the development of new strategies for the diagnosis and treatment of human disease. Ultimately, this new discipline is expected to lead to a predictive, individualized approach to patient care and to facilitate the selection of treatment modalities that are most likely to benefit the individual patient.

Mass spectrometry and array-based protein and antibody approaches are at the core of a rapidly expanding worldwide effort to find clinically useful protein biomarkers in human tissues and body fluids. This effort involves major challenges in sample collection, preparation, data acquisition, throughput, and quantitative, statistically valid data analysis. The overarching goal is to develop a biomarker pipeline from basic research through validation to clinical use where the goals, requirements, and methods at each stage are clearly delineated and understood. Although this lofty goal has yet to be fully addressed, we remain optimistic that the challenges can

and will be met by well integrated teams of basic research scientists, clinicians, statisticians, and developers of new technology. We compiled this special issue of *Molecular & Cellular Proteomics* (MCP) entitled “Biomarker Discovery and Clinical Proteomics” in the hopes of stimulating the process.

MCP recognized early on the potential of clinical proteomics and committed the journal to supporting this promising and far-reaching discipline by providing a forum to foster, nurture, and guide its development. Four years on from the publication of the first special issue on clinical proteomics (June 2003, Vol. 2, No. 6), we are happy to present the fourth issue in our series of special clinical issues. Most of the contributions were invited and derive in part from presentations at the 2005 Asilomar Conference on “Biomarker Discovery and Validation: from Bench to Bedside” organized by Steve Carr and Leigh Anderson. We also include four research reports selected from direct submissions to the journal. The issue is divided into four major sections on biomarkers of disease and conditions, proteomics data analysis, methodologies, and a meeting report. The papers address a broad sweep of advances in technologies, sample preparation methods, data analysis approaches, and applications for disease detection and prognosis. We have also included a meeting report on the National Cancer Institute’s efforts to stimulate a community effort around production, characterization, and cataloging of antibody reagents useful for early detection, treatment, and monitoring of cancer. This is a critically important effort that needs our full attention and support.

We extend our gratitude to the contributors for their willingness to provide the manuscripts and to the staff of *Molecular & Cellular Proteomics* for their expeditious and efficient handling of the manuscripts.