Preface

The next revolution in molecular medicine is the application of molecular profiling to individualized patient therapy. Molecular profiling technology has advanced dramatically, particularly in the field of cancer tissue biomarkers. It is now possible to gather complex genomic and proteomic information from a routine clinical needle biopsy or surgical specimen. This means that translational research scientists can finally begin to address urgent applied research questions that were not possible in the past: (a) How can tissue molecular information be gathered in a reliable and reproducible fashion that is suitable for routine application to the clinic? (b) How does the molecular signature of diseased tissues provide insights into pathogenesis, prognosis, and therapeutic options? (c) What is the best means of combining molecular data with other classes of clinical data (imaging, pathologic staging, clinical chemistry panels) to optimize the treatment plan for the individual patient? (d) How can new classes of clinical research trials be created that are biomarker guided, hypothesis driven, and individualized? The purpose of this volume is to provide an accelerated tutorial to assist students, entrepreneurs, new investigators, and established investigators who want to quickly become versed in, and immersed in, the entire process from discovery to clinical trial validation and commercial public benefit. Our internationally recognized chapter authors have provided the background science, the vision, and the practical experimental protocols, with tips and troubleshooting guides. Since the aim is to span the full process from discovery to commercialization, our practical guides are not limited to experimental methods. We have included tutorials on patents and intellectual property, small business development, FDA review guidelines for molecular profiling, and grant writing tips for investigators seeking funding in translational research.

Molecular Profiling is designed to step the reader through a project/experiment in molecular medicine. The protocol chapters describe detailed techniques for evaluating tissue samples, tissue collection and storage, analytical platforms, and bioinformatics/biostatistics. The narrative chapters are designed to provide the reader with a well-rounded discussion of intellectual property issues in biotechnology, human subjects research requirements, regulatory agency approval processes, and an overview of technology transfer (patent) issues. Although other books have been published covering the topics of genomic profiling, or protein chemistry, we believe this is the first book dedicated to incorporating genomics, proteomics, and bioinformatics with experimental protocols and detailed discussions of future requirements and challenges for commercialization and practical use in the field. An emphasis is placed on tissue-based molecular profiling, a rapidly emerging field that is not covered in pathology text books.

Molecular Profiling covers eleven topics in relation to human disease: Cancer medicine and medical ethics relevant to individualized therapy, genomics, proteomics, microscopic imaging, bioinformatics, tissue preservation/biobanking, individualized therapy regimens, intellectual property, regulatory approval, business development, and grant funding in translational research. A set of core Chapters 1–24 covering genomics, proteomics, imaging, and bioinformatics, illustrate current laboratory protocols for generating data relevant to molecular medicine. Each of these disciplines is complementary and the grouping simply

provides a means for differentiating the classes of molecular analytes. The four topics covered in Chapters 25–28 are unique aspects of this volume of the Methods in Molecular Biology series. These latter chapters discuss, in a narrative or tutorial style, future real-world needs in personalized molecular medicine. Important points are highlighted in the Notes section for each chapter.

Although many of the techniques discussed in this volume use commercially available reagents and instrumentation, it is imperative for the user/reader to understand the principles and nuances of these techniques, because they are designed for use with irreplaceable human tissue specimens. In an attempt to provide basic assay information, we have included overview principles in the introduction to each analytical chapter as well as providing troubleshooting tips and tricks for the experienced scientist.

We hope that the readers of this volume will use it as a practical guide at the lab bench as well as the boardroom. The intended readership spans the range of scientists, pathologists, oncologists, residents, biotechnologists, medical students, and nurses involved in clinical trial research. We have a personal hope that this volume will attract new investigators who can apply their creative talents to realize the promise of individualized molecular medicine.

We thank our esteemed chapter authors for their valuable contributions to this volume.

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