
Preface

The first edition of *Molecular Profiling* (published in 2012) was at the forefront of the personalized medicine movement. The first edition included reviews of genomics and genomic profiling, technologies which in the intervening years have rapidly evolved into routine clinical assays for detecting mutations. Mass spectrometry for protein profiling has also evolved into sensitive and specific multiple reaction monitoring assays, enabling quantification of proteins without antibody-based methods, while tumor staging and grading and tissue preservation continue to be important aspects of molecular profiling. As you can see from these examples, staying current in molecular profiling requires lifelong learning and incorporating “routine” laboratory analyses with cutting-edge technologies. Hence, when Professor John Walker, editor for the *Methods in Molecular Biology* series, inquired as to my interest in editing an updated version of this book, I was honored that the readers found the first edition informative and that there was sufficient, continuing interest in molecular profiling for an updated version. However, I also knew that the second edition would require many updates to the protocol chapters to reflect the current state of the art in molecular profiling.

The purpose of this revised volume is to provide both an update on technology and 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. The aims of the first and second edition are the same: to span the full spectrum of molecular profiling from tumor staging and grading through biomarker discovery to commercialization. The practical guides are not limited to experimental methods. I have included tutorials on tumor staging, ethics, patents and intellectual property, product development, innovative clinical trial designs, and grant writing tips for investigators seeking funding in translational research.

Molecular Profiling, second edition, includes 17 new chapters and 9 revised/updated chapters. The new chapters cover some “tried-and-true” laboratory methods such as PCR and scanning electron microscopy. The second edition also includes updated versions of antibody validation and Western blotting. I had two reasons for including these “standard,” often kit-based, laboratory methods: (1) understanding the science behind the “kits” can help solve many problems encountered in assay development, and (2) the book is intended for a wide audience, including students and physician-scientists. The 17 new chapters cover laboratory methods relevant to human disease: microsatellite analysis, somatic mutation analysis, proteomic bioinformatics, microscopic imaging, preservation of bone tissue for molecular profiling, glycomics, metabolomics, immunohistochemistry, FISH, ELISA development, and multiple reaction monitoring mass spectrometry.

Chapters 1–3 introduce the reader to clinical medicine through a primer on tumor staging and grading, ethics in medicine, and clinical trial design. These chapters have been updated to address the current relevant information and issues. For example, the chapter on clinical trials discusses examples of innovative trial design in which data generated during the clinical trial can be used to modify therapies administered to the patients as the trial is accruing patients.

A set of core chapters (4–23) 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. An emphasis is placed on tissue-based molecular profiling, which is the core of personalized medicine. 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.

The three topics covered in Chapters 24–26 are a unique aspect of this volume of the *Methods in Molecular Biology* series. These latter chapters discuss, in a narrative or tutorial style, real-world needs in personalized molecular medicine. The narrative chapters are designed to provide the reader with a well-rounded discussion of intellectual property issues in biotechnology, human subjects research requirements, tips for grant writing in translational research, and an overview of technology transfer (patent) issues. As with the protocol chapters, important points are highlighted in the Notes section for each of the narrative chapters.

I hope that the readers of this second edition of *Molecular Profiling* will use it as a practical guide at the lab bench as well as in the classroom. The intended readership spans the range of scientists, pathologists, oncologists, residents, biotechnologists, medical students, and nurses involved in clinical trial research.

I would like to express my sincere gratitude to my editorial assistant, Emily Espina, who provided excellent grammar editing. I truly appreciate, and thank, all my authors for their time and effort in compiling and submitting new and updated chapters. Their collective contributions and input have greatly expanded the scope and depth of the book. I thank Lance Liotta, my co-editor on the first edition, who supported me with the utmost respect and trust, while I pursued this solo editing endeavor.

I anticipate that this revised volume will attract new investigators, and invigorate experienced researchers, who can apply their creative talents to realize the promise of individualized molecular medicine. I hope you find this revised edition a useful and informative guide for your molecular profiling adventures.

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