Preface

We are currently experiencing a fundamental shift in the way in which we approach the characterization of cancer. Never before has the make up of cancer tissues and individual cells been so exhaustively researched and characterized. We are now capable of producing molecular “fingerprints” that characterize the expression of all known and unknown genes within tumors and their surrounding tissues. More than 30,000 different genes may be measured in each patient’s tumor in a single experiment. Simultaneously, novel therapies that exploit the molecular roadmap have been developed and are now being offered to patients. These novel agents, such as Glivec, Herceptin, Iressa, and others, specifically target individual genes within tumors and can produce dramatic responses in some patients. These drugs are only the forerunners of a coming tidal wave of novel therapeutics that individually target specific molecules within cancer cells—more than 300 such agents are currently in phase I or II clinical trials. This is an exciting time for cancer specialists and patients alike.

However, if we have learned anything from the past 50 or more years of research into cancer, it is that Lord Beaverbrook, in founding the British national health service in the 1950s, was frighteningly prescient when he defined the primary goal of health care to be “Diagnosis, Diagnosis, Diagnosis.” Now, more than ever, it is essential that appropriate diagnostic methods and approaches are applied to the selection of patients for treatment. Each of the novel agents above, and those in development, requires, almost by definition, the development of an appropriate molecular test to characterize the patients who are most likely to benefit. For example, Herceptin, which is producing dramatic effects in the treatment of advanced breast cancers, targets the HER2 oncogene. In patients who display this genetic abnormality, response rates are between 25 and 35%, in unscreened breast cancers the predicted response rate would be 3–5%. We are faced, therefore, with the likelihood of an exponential rise in requests for molecular characterization of tumors to identify gene mutations, losses, amplifications, rearrangements, and so on. Experience has shown that many diagnosticians are currently untrained in the specific technical areas critical to this relatively novel field of “Molecular Diagnostics.” Molecular Diagnosis of Cancer aims to provide not only an academic, but also a fundamentally technical insight into this novel area of diagnostic medicine. We are particularly grateful to those who have taken time to contribute to this volume, their efforts have created a comprehensive
overview of current molecular diagnostic approaches and have, by providing
detailed technical protocols, produced a laboratory handbook to facilitate the
introduction of these techniques.

Although this volume does not seek to cover every possible aspect of mo-
lecular research, it does focus on specific molecular techniques that will pro-
vide an invaluable aid to those seeking to implement novel technologies into
their diagnostic practice. The detailed step-by-step protocols and explanatory
notes will, we hope, enable many more laboratories to enter this new and excit-
ing arena.

In addition to those who have contributed to *Molecular Diagnosis of Cancer*
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