
Preface

Infectious diseases represent one of the main threats to public health today. Though improvements in antibiotic and antiviral therapy have been realized during the last years, pathogens were nonetheless able to develop mechanisms rendering them resistant towards specific treatments. Furthermore, a variety of recently discovered microorganisms, such as *Helicobacter pylori*, hepatitis D and E, and HIV-2, have been accepted as etiological agents of human diseases.

In order to allow a rational and specific use of antibiotic and antiviral pharmaceuticals, the detection and identification of the causative pathogen is of major importance and will require increasingly accurate diagnosis with rising demands for the specificity, sensitivity, and speed of the corresponding assay. The revolutionary progress associated with molecular biology-based technology, such as the detection of DNA or the manufacture of recombinant antigens or antibodies, has already gained major advantages in medicine and will contribute to the development of improved assay systems.

Basically, there are three different ways for the specific detection of a given pathogen: (1) the detection of the pathogen itself (e.g., by microscopy, culture or biochemical characteristics); (2) the direct detection of selected components of the pathogen (e.g., nucleic acids, antigenic proteins); and, in an indirect way, (3) the detection of specific antibodies generated by the infected organism.

Recently published books in the field of clinical microbiology are substantially focused on different aspects of PCR. As a consequence, most of them lack in highlighting the equal methodical progress of serodiagnosis by recombinant proteins and antibodies. This is of particular importance in the proteomics era. With the permanently increasing demands of both the cost per test and the expressiveness of the results, the use of recombinant antigenic proteins and recombinant antibodies for the serodiagnosis of infectious diseases has gained more and more importance. Large quantities of recombinant proteins can now be produced at comparatively low cost in suitable bacterial or cell culture systems. A variety of molecular biological techniques are available at present, and have proved to be advantageous in the preparation of recombinant proteins.

Apart from a brief description of the principles of immunological assays, the book describes both established and novel strategies that have been applied successfully in identification of valuable diagnostic markers, epitope mapping, the characterization of immunomodulatory components, the production and purification of recombinant antigens and their use as diagnostic reagents in immunological assays. Promising biosensor technology and recent developments in

antibody engineering are also covered. In addition to these straightforward techniques, the book addresses basic problems of serological laboratory diagnosis as well. Some duplication of important topics has been purposely introduced to offer the reader several approaches to the same problem. Significant scientific progress has been achieved since the first edition of *Molecular Diagnosis of Infectious Diseases*. The genomic era picked its peak with the publication of the complete sequence of the human genome. Sequencing bacterial genomes has now become a routine task. Bioinformatics has been accepted as an invaluable tool for managing the large amount of data generated by high-throughput analysis, genomics and proteomic studies. Proteomics has seen a renaissance underlining the significance of proteins and protein based techniques in science and clinical diagnostics. Hence, special emphasis is placed on proteomics and the characterization and modification of proteins.

Instead of focusing on particular infectious agents, it is hoped that the collection of detailed protocols providing comprehensive and up-to-date information will be especially useful to researchers and students to get familiar with the principles of Molecular Diagnostics, and guiding them to set up test systems tailored to their specific needs.

Since molecular biology-based tools are subject to permanent improvement, this volume does not attempt the impossible task of treating all aspects of the various experimental approaches in the field. Rather, it depicts a kind of cross-section of the actual possibilities for the conception of refined assays.

Undoubtedly further progress in the rapid and specific detection of pathogenic organisms is expected with the help of modern molecular biology, and the future will show what kind of assay and what kind of diagnostic marker will prove useful for individual clinical situations.

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