Molecular Microbiology
DIAGNOSTIC PRINCIPLES AND PRACTICE
THIRD EDITION
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In the 5 years since the 2011 edition of this book, the molecular diagnostics landscape has changed dramatically. In the 1990s, molecular diagnostics was the domain of only a few reference laboratories; it took almost 20 years for these techniques to make their way into about half of the CLIA high-complexity laboratories in the United States. The full potential of this technology was slow to be realized largely because the methods used by these laboratories were not capable of delivering on-demand results or being conducted at the point of care. Over the past year, with the advent of CLIA-waived molecular testing spurred on by the inexorable force of innovation, molecular diagnostics have become increasingly democratized to the extent that physician office laboratories and sexual health clinics are now performing molecular testing on the premises, often delivering results in minutes or a few hours.

Laboratory professionals may at times find themselves a bit bewildered in this rapidly evolving landscape. Adding to this, enter next-generation sequencing (NGS) technology, as described in several chapters in this book (chapters 2, 3, 5, 6, 10–14, and 53). NGS-based analysis of microbial genomes and populations is in some ways similar to where PCR was in 1987: full of opportunities and challenges. For the first time, identification of the full range of pathogens—viruses, bacteria, fungi, and protozoa—can be addressed by using the same core technology. Microbial population analysis can be carried out at unprecedented depth, opening up the field of metagenomics (chapters 10–14). Whole-genome analysis goes beyond organism identification to predict drug resistance and detect pathogenic determinants. As diagnosticians, it seems likely that as this field evolves, so will our job descriptions. Still, much progress remains to be made before NGS can move beyond its current status as a research tool. NGS systems need to become more automated and less expensive to operate. The analysis of complex data sets provided by these systems needs to be simplified; the interpretation of results cannot require a PhD in bioinformatics for delivery of routine results. However, as complex as it is now, NGS too will eventually become democratized by the integration of workflow automation, improvements in sequencing technology, and information technology (IT).

Speaking of which, IT itself is about to play an increasing role in how and to whom our results are delivered (section X). A rapid molecular result is only as good as the downstream action taken in the treatment and management of patients. As we speak, patients in London, along with providers, are getting “push notifications” of results from their sexual health tests, resulting in a dramatically shortened time to therapy. Cloud-based aggregation of molecular test data is providing snapshots of emerging pathogens and drug resistance in real time by collecting de-identified test data directly from testing platforms. From the respiratory cloud to the digital cloud, we are watching the emergence of a new generation of global surveillance capabilities which will be of enormous public health benefit. Rapid detection technologies are also likely to evolve in the direction of on-demand multiplexing for simultaneous detection of treatment-informing targets. The convergence of rapid molecular assays with improvements in IT to deliver actionable information to health care providers is becoming a reality.

In 2015, the White House announced a $20 million prize for innovative diagnostic tests that will lead to more precise antimicrobial therapeutic decisions. In addition, the United Kingdom has announced the Longitude Prize, a challenge with a £10 million award for developing a point-of-care diagnostic test that also will identify when antibiotics are needed and which one to use. Thus, it seems that the importance of molecular diagnostic testing is finally being appreciated at the highest levels, especially to address the global problem of antimicrobial resistance. Let’s not disappoint them.

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