

## Advances in Microbiology

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Rapid identification of microorganisms in the clinical microbiology laboratory can be of great value for selection of optimal patient-management strategies for infections caused by bacteria, viruses, fungi, mycobacteria, and parasites. The switch to tailored therapy minimizes risks of antibiotics, namely, disruption of normal flora, toxic side effects, and selective pressure. There is a critical need for new technologies in clinical microbiology, particularly for bloodstream infections, in which associated mortality is among the highest of all infections. The field of microbiology is moving exceptionally fast, in part because it can take full advantage of the new developments in microscopy, computational biology, synthetic biology, lab-on-chip approaches, and single-cell technologies. Advanced microbiology technologies are rapidly changing the ability to diagnose infections, improve patient care, and enhance clinical workflow. These tools are increasing the breadth, depth, and speed of diagnostic data generated per patient, and testing is being moved closer to the patient through rapid diagnostic technologies, including point-of-care (PoC) technologies.

While select stakeholders have an appreciation of the value/importance of improvements in the microbial diagnostic field, there remains a disconnect between clinicians and some payers and hospital administrators in terms of understanding the potential clinical utility of these novel technologies. Therefore, a key challenge for the clinical microbiology community is to clearly articulate the value proposition of these technologies to encourage payers to cover and hospitals to adopt advanced microbiology tests. Specific guidance on how to define and demonstrate clinical utility would be valuable. Addressing this challenge will require alignment on this topic, not just by microbiologists but also by primary care and emergency room physicians, infectious disease specialists, pharmacists, hospital administrators, and government entities with an interest in public health. Both the pharmaceutical and diagnostic manufacturing industries will also be required to be involved in orchestrating the generation of clinical-utility evidence. Given that hospital administrators often prefer to undertake a trial period with new technologies to gain first-hand experience, diagnostic technology manufacturers may need to pursue collaborations for this to be actively achieved. Furthermore, they can work to guide not only microbiologists but also facilitate early partnership with those in clinical and financial roles about the design of studies, which could help illustrate the clinical utility of these deployed tools in a fair and balanced way. They can also play a role in helping community hospitals understand

where to find clinical-utility information and how to share clinical-utility information so that advanced care approaches are not limited to academic medical centers alone. Additionally, pharmaceutical leaders in the microbiology space may be required to actively participate in data gathering and publication, supporting the concept that next-generation antimicrobials may be more effective, particularly if paired with the most advanced diagnostic technologies. This will likely require active collaboration between pharmaceutical and diagnostic companies to ensure the clinical-utility benefit of appropriate prescribing of next-generation treatments is influenced by novel technologies entering the space.

### Technology trends

The advances and innovations in microbial diagnostic technologies over the last decade are beginning to have a significant impact on the way one diagnoses and manages infectious diseases. In the coming years, an additional cohort of new microbial diagnostics is expected to enter the space. Technologies that include advanced genomics, proteomics, and rapid susceptibility tests are expected to cause dramatic changes by tackling some of the most important problems for microbial diagnostics. Additionally, advanced analytic tools, such as artificial intelligence and machine learning, can enhance the information extracted from the data these technologies collect. For example, the menu of culture-independent nucleic acid amplification tests and syndromic panels is expanding. These advances will likely favor the deployment of culture-independent reporting of antimicrobial-resistance (AMR) determinants, including the creation of a clear correlation of AMR genotype to antimicrobial susceptibility phenotype/MICs. Also, automated microscopy is being leveraged for early detection of sepsis by detection of morphological changes in monocytes indicative of dysregulated immune response or morphological changes in bacteria, indicative of drug susceptibility. Next-generation sequencing (NGS) methods and proteomics (e.g., MALDI-TOF) are expected to impact key diagnostic segments in the future. In contrast to PCR panels, these methods have the potential for hypothesis-free detection of pathogens and host-response markers. NGS-based analysis of pathogens further allows phenotypic prediction, such as detection of AMR determinants, virulence factors, and mobile genetic elements. Also, whole-genome sequencing of isolates by next-generation sequencing allows strain typing at nucleotide-level resolution for epidemiological studies and infection control.