

Statement to the Clinical Laboratory Improvement Advisory Committee
November 1, 2017

Five years ago, Microbiologics issued a statement to the Clinical Laboratory Improvement Advisory Committee (CLIAC) on the topic of culture-independent microbiology diagnostics. We are pleased to see the CLIAC revisit this issue today.

Microbiologics is the world's leading provider of highly accredited biological reference materials and innovative molecular controls for assay development and instrument validation as well as routine, ready-to-use quality control testing of diagnostic assays in clinical, pharmaceutical, food and environmental laboratories.

In 2012, we offered observations on the increased use of culture-independent microbiology diagnostics. We noted that, depending on the pathogen, certain culture-independent microbiology diagnostics, such as DNA extracts, may benefit the public health and are generally quicker and safer to use. We noted the greater availability of mass spectrometry for use in quality control. We also expressed concern over the lack of standards in quality control in culture-independent microbiology diagnostics. This lack of standards, we noted, leads to too much variability. There was concern that manufacturers are producing not only the test kits, but their own quality control for those kits, which called into question the needed measure of precision, reproducibility and impartiality.

While the challenges of 2012 still exist, we find that there are additional concerns to address. Controls are necessary for diagnostics and the development of antimicrobial therapeutics. Both internal controls (with a description of its specific function within an evaluation system) and external controls (as recommended or provided to the user) are important testing elements. Validation through quality control will help to pinpoint possible failures in test systems, test methods, environmental conditions and laboratory personnel performance.

We repeat - without standards, variability in quality control for diagnostics is too great.

The variability of reference methods needs addressing. For example, minimal inhibitory concentration (MIC) values are a useful way of evaluating the susceptibility of a strain. While normal variation in the strain and performance is permitted, the MIC value must be scientifically sound. The use of standardized controls can assist in resolving these issues of variability. Controls help determine if the evaluated range is realistic, but not so rigid that clinical laboratories are unable to meet it.

There must be broad availability of recent isolates for research and commercial investigation.

Technology is evolving rapidly for next generation sequencing diagnostics. In the quality control area, there is a need to ensure that standard reference materials are available to confirm the validity of the performance characteristics of these devices. Current reference databases, such as FDA-ARGOS and NIST microbial standard reference materials, are not at a capacity to meet current diagnostic needs. This is a challenge for new and emerging technologies.

The CDC-FDA Antimicrobial Resistance Isolate Bank is an important resource for obtaining microbial pathogens. It is an innovative, governmental approach that, according to the CDC, has led to the sharing of more than 55,000 isolates since its inception. It deserves support.

It is important to note that while these public sources are critical, they do not and should not serve to replace commercially available options.

Thank you for the opportunity to address these issues with you.