



Statement to the Clinical Laboratory Improvement Advisory Committee August 30, 2012

Microbiologics appreciates the Clinical Laboratory Improvement Advisory Committee (CLIAC) for continuing to monitor issues impacting the public health.

Microbiologics produces a uniquely qualified array of the most highly accredited biological reference materials. We specialize in offering lyophilized microorganism preparations for use in the food, clinical, pharmaceutical, cosmetic, dietary supplement, water, environmental and educational industries. It is the mission of Microbiologics to provide the highest quality biomaterials for a safer, healthier world. It is in this vein that we offer comments regarding the increased use of culture-independent microbiology diagnostics and its impact on public health.

In February 2007, a CLIAC Workgroup, chaired by Barbara Robinson-Dunn, PhD, reported the results of its study of key issues related to the impact of rapid and molecular technologies for infectious disease agents on public health. The Workgroup identified an extensive list of benefits and challenges to public health in this then-emerging area of testing.

Now, five years later, many of these issues remain open for deliberation despite advances in technology and progress in communication. As a leading provider of biological reference materials for use in quality control and proficiency testing, Microbiologics offers these observations focused specifically on the increased use of culture-independent microbiology diagnostics:

1. Depending on the pathogen, culture-independent microbiology diagnostics, such as DNA extracts, may benefit the public health. For some pathogens, such as *Bacillus anthracis*, *Mycobacterium tuberculosis*, and other BSL-3 pathogens, the use of DNA extracts are generally quicker and safer to use. For pathogens that are slow to grow in humans, such as *Giardia lamblia*, creating quality controls can be expensive and time intensive. In these situations, the public health may be best served through the use of culture-independent microbiology diagnostics.
2. Although centered more on applied analytical and clinical research areas, there is a greater availability of mass spectrometry for use in quality control than there was five years ago. It is our observation that the use of mass spectrometry has increased for European clinical laboratories due to advances in technology and economies of scale.
3. Finally, and most importantly, there is a concern over the lack of standards in quality control in culture-independent microbiology diagnostics. Because of this absence, there is too much variability in quality control for these tests. In many cases, manufacturers are producing not only the test kits, but their own quality control for those kits. Assessing one's own diagnostics does not provide the needed measure of precision, reproducibility or impartiality.

Even at Microbiologics, we use controls from our competitors when testing strains in our sister laboratory.

Microbiologics has supported a study, which will soon be released, examining differences in manufacturers' quality control. Once available, we will be glad to share the results with this Committee.

Thank you for the opportunity to submit these comments to you.