



**AMERICAN  
SOCIETY FOR  
MICROBIOLOGY**

*Public and Scientific Affairs Board*

**Statement from the American Society for Microbiology  
Before the Clinical Laboratory Improvement Advisory Committee  
on  
Appropriate Quality Control for Microorganism Identification Systems**

**Presented by  
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Committee on Professional Affairs  
Public and Scientific Affairs Board, ASM**

**February 17, 2005**

The American Society for Microbiology (ASM) welcomes the opportunity to assist CLIAC and the associated federal agencies with the issue of appropriate quality control (QC) for microorganism identification systems used by clinical microbiology laboratories.

The current requirement under CLIA is to test each substrate or reagent in microbial identification panels for positive and negative reactivity with each batch, lot number and shipment. This requirement entails the expenditure of significant financial and personnel resources. On January 7, CDC/CLIAC staff contacted ASM to request assistance in collecting performance data from different microorganism identification systems (including instrument-based and manual systems) to determine the frequency with which QC failures occur. Analysis of the data will determine whether the current QC testing requirement under CLIA is excessive and fails to identify problems more effectively than more limited testing would.

ASM looks forward to working with CDC and CMS to survey users of microorganism identification systems and to analyze the data to determine whether QC requirements can be altered without compromising patient care.