



# Quality Control for Commercial Microbial Identification Systems

Clinical Laboratory Improvement Advisory Committee

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Nancy Anderson, MMSc, MT(ASCP)  
Division of Laboratory Systems  
Centers for Disease Control and Prevention

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## Quality Control (QC) Requirements for Microbial Identification Systems (MISs)

- CLIA requires the laboratory to check each batch (in-house), lot number (commercial) and shipment of reagents, discs, stains, antisera and **identification systems** for positive and negative reactivity and graded reactivity, if applicable
- CLIA defines identification systems as “systems using two or more substrates or reagents, or a combination”
- Varying numbers of control organisms are needed to check positive and negative reactivity for each substrate/reagent on MISs that include multiple reactions



## Previous Consideration of MIS QC

- Laboratories expressed concerns to CLIAC in late 2004 suggesting the CLIA QC requirements for commercial MISs are excessive
- A manufacturer recommended one QC organism as adequate to check each MIS shipment/lot number
- ASM conducted a survey of microbiology laboratories to determine the QC failure rates of commercial MISs and reported results to CLIAC in 2006
- Based on the survey, ASM recommended that CLSI develop guidelines for appropriate MIS QC



## Clinical and Laboratory Standards Institute (CLSI) Subcommittee

- April 2006 – CLSI recommended a subcommittee develop guidelines for QC of commercial MISs
- Subcommittee:
  - CDC
  - MIS manufacturers
  - CMS
  - Microbiologists
  - FDA
- August 2008
  - Final document was approved through the CLSI voting process
  - Publication of *CLSI M50: Quality Control for Commercial Microbial Identification Systems*



## Scope of CLSI M50

- M50 includes responsibilities for commercial MIS manufacturers, distributors, and laboratory users
- The streamlined QC approach described in the document may be implemented for MISs of proven reliability
- M50 assumes that MIS performance is monitored by overall quality assurance programs
- Although it may be used internationally, M50 is geared towards U.S. laboratories that are subject to CLIA



# Manufacturer Responsibilities

- Register with the FDA and comply with quality system standards (ISO 13485) and FDA Quality System Regulations (QSRs)
- Provide documentation of compliance to MIS users
- Develop an agreement with the distributor to ensure proper MIS storage, shipping and handling
- Provide instructions that include recommended QC organisms and justification for streamlined QC, as applicable



# Distributor Responsibilities

- Comply with specifications for MIS storage and handling
- Maintain documentation of compliance
- Communicate complaints to the manufacturer as appropriate



# User Responsibilities to Implement Streamlined QC

- Maintain documentation of manufacturer compliance with ISO 13485 and QSRs
- Either:
  - Perform and document MIS verification as required by CLIA; or
  - Conduct a historical review of QC performance as described, with at least 95% reagent/substrate results being correct
- Continuation of streamlined QC is based on ongoing documentation and testing key indicator strains with each batch, lot number and shipment, as described in manufacturer's instructions



## Next Steps for M50

- Manufacturers need to revise MIS instructions to identify key indicator strains to be tested under streamlined QC
- CMS intends to allow for streamlined QC as an exception to the CLIA requirements
- CLIA surveyors will be notified of the change and the exception will be incorporated in CMS guidelines
- CMS-approved accreditation organizations may then evaluate the streamlined QC approach and may incorporate it in their standards



Implementation of streamlined QC for MISs is an important process where all laboratory partners need to play an active role!

**Thank you!**

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