DADE BEHRING

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Clinical Laboratory Improvement Advisory Committee (CLIAC)

Re: CLIAC Meeting – February 16th -17th , Atlanta, GA; Introduction to appropriate quality control for diverse and evolving test systems, including microbiology identification systems.

Dade Behring Inc., a manufacturer of in-vitro diagnostic devices, respectfully submits comments to the Clinical Laboratory Improvement Advisory Committee for the upcoming CLIAC meeting.

Dade Behring appreciates CLIAC's efforts to investigate the impacts on medical and clinical laboratories and manufacturers imposed by the existing guidelines for quality control for microbiology identification systems. We support the incorporation of appropriate guidelines for microbiology identification quality control and would appreciate input for the following:

- Defining roles and responsibilities for the manufacturer and the end-user in regards to quality control requirements.
- Streamlining the end-user quality control requirements while still confirming acceptable performance.
    - e.g. – eliminating the overall requirement for a positive and negative reaction for each substrate.
- Reducing the end-user quality control frequency, as appropriate, for manufactured microbiology identification systems based upon risk, performance, stability, etc.
- Allow alternate approaches to identification quality control
    - e.g. – reagent QC testing, chemical assays, etc.

I would appreciate the opportunity to attend the upcoming meeting and become involved in discussions regarding microbiology identification quality control requirements.

If you have any questions, please contact me at (916) 374-3183 or by email at rob_eusebio@dadebehring.com.

Regards,

Robert Eusebio

Robert Eusebio
Regulatory Affairs Manager
Dade Behring Inc.
MicroScan Microbiology Systems

Microbiology Identification Systems

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- Current requirements:
  - Costly
    - 24 – 36 Substrates on Identification Systems
  - Burdensome
    - Time, Resources, etc.
  - Is all the testing Value Added?
  - Testing requirements similar to other products
- What is the role of Manufacturer vs. User?

Microbiology Identification Systems Quality Control

- Purpose of Quality Control
  - Monitoring:
    - Precision (repeatability) & accuracy
    - Performance of reagents
    - Performance of persons testing product

Microbiology Identification Systems Quality Control

- Manufacturer's roles
  - Stability
  - Potency
  - Compliance with U.S. FDA Quality System Regulations
  - Integrity
  - Accountability and Traceability

Microbiology Identification Systems Quality Control

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  - Accountability and Traceability
  - Provide information on what issues could occur with product (e.g. shipping, temperature)

Microbiology Identification Systems Quality Control

- End-User's Roles
  - Storage
    - Prevent deterioration
  - Proficiency of personnel
  - Adherence to procedures
    - Inoculum preparation
    - Incubation conditions
    - Interpretation of end points
  - Responsible to examine for deterioration, discolored, etc. based on Manufacturer's guidelines

Microbiology Identification Systems Quality Control

- Questions
  - Pos & Neg result for every substrate
  - Pos & Neg result for reagents – using bacterial isolates
  - Value of a Neg result
  - Focus testing adds more value on testing key significant indicator substrates

Microbiology Identification Systems Quality Control

- Manufacturer could provide:
  - Recommendations for routine monitoring
    - e.g. Pseudomonas aeruginosa for Imipenem testing – AST
  - Provide Key Indicator Substrates & assist in how to evaluate – Focus Testing
    - e.g. Substrate dependent on Temperature, Inoculum, shipping excursions, etc. – therefore value added in testing

Microbiology Identification Systems Quality Control

- Recommendations:
  - Reduced frequency of testing required
  - Reduced quantity of testing required
  - Manufacturers provide guidelines to end-users to evaluate "bell-weather" or key indicator identification substrates
  - Evaluate how often Identification Substrates are "out-of-range" to determine if testing adds value or is required and how frequently tested