

Update on ASM Survey of QC Failures with Microorganism Identification Systems

Presented to Members of CLIAC

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Committee on Professional Affairs

ASM Public and Scientific Affairs Board

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Update on ASM Survey of Micro ID Systems

- CLIA requires laboratories to test each substrate or reagent in microbial identification panels for positive and negative reactivity with each batch, lot number and shipment
- ASM was asked to collect data on the number of QC failures that occur to assist CLIAC in recommending a policy change regarding the appropriate amount of QC required

Update on ASM Survey of Micro ID Systems

- Complex issue/concerns raised about lack of FDA oversight on microorganism ID Systems
- ASM took the issue to its PSAB Committees and to its Division C membership for discussion
- ASM decided it was important to collect data for surveillance purposes
- ASM has discussed with CLSI* the use of its consensus process to determine appropriate QC
(*Clinical Laboratory Standards Institute/formerly NCCLS)

Update on ASM Survey of Micro ID Systems

- Survey was pretested July 20 – August 10
- Pretest group consisted of members of ASM PSAB Committees on Professional Affairs and Laboratory Practices (16)

Update on ASM Survey of Micro ID Systems

Survey Instrument General Questions

- Laboratory type (i.e. hospital, public health, commercial, etc)
- Size of laboratory (i.e. culture volume; number of FTEs)
- Laboratory accreditation/certification and board certification of laboratory director
- Educational degrees of laboratory personnel who oversee QC

Update on ASM Survey of Micro ID Systems

Survey Instrument QC Related Questions

- Type of Micro ID System(s) used by laboratory (survey instrument included a key with a list of sixty-nine identification systems)
- Number of lots of each ID System used during two year period of 2003-2004

Update on ASM Survey of Micro ID Systems

Survey Instrument QC Related Questions

- Number of QC organisms tested for each ID System
- Number of times a lot was replaced by the manufacturer due to a QC failure
- Note biochemical test(s) that failed QC
(asked to differentiate between a true test failure and a failure of a QC organism to act properly)

Update on ASM Survey of Micro ID Systems

Results from pretest group

- 11/16 surveys were returned
- 10/11 laboratories tested >5000 cultures/year
- 9 laboratories were hospital laboratories, 1 was a public health laboratory and 1 was a commercial reference laboratory
- Degree of QC administrator – none were below bachelor's level

Update on ASM Survey of Micro ID Systems

Results from pretest group (continued)

- Majority used more than 5 identification systems in their laboratories (range 2-12 systems)
- Types of systems used
 - Gram Positive (12)
 - Gram Negative (10)
 - Neisseria/Haemophilus (3)
 - Anaerobic bacteria (2)
 - Common UTI bacteria (1)
 - Yeasts (5)

Update on ASM Survey of Micro ID Systems

Results from pretest group (continued)

- Total number of lots used: 668
- Range of QC organisms used/system: 1-9
- No failures were reported

Update on ASM Survey of Micro ID Systems

Next Steps

- Work with CMS to obtain a list of microbiology laboratories
- Work with CDC to determine the appropriate sample size
- Approximate timeline
 - Mail surveys at the end of September
 - Collect data in October
 - Work with CLSI Area Committee on Microbiology in October/November

Update on ASM Survey of Micro ID Systems

Thank you CLIAC staff who aided ASM in the drafting of the survey instrument and who have provided much guidance

- Rhonda Whalen, CDC
- Nancy Anderson, CDC
- Stacey Cooke, CDC
- CDC Statisticians
- Judy Yost, CMS