

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

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 seventy-one identification systems)
- Do you perform QC as required by CLIA?
- Number of lots QC tested for each ID System used during January 1, 2004 – October 15, 2005

Update on ASM Survey of Micro ID Systems

Survey Instrument QC Related Questions

- Number of times an ID system failed QC
- Note organism name and strain that failed QC*
- Note biochemical test(s) that failed QC*
- Did you ask the manufacturer to replace lot?

*ASM wanted respondents to differentiate between ID system failure and organism failure

Update on ASM Survey of Micro ID Systems

Survey Results

- Total number sent: 1000
- Total number responses received: 309
- Total number of useable surveys: 292

Return Rate

- Approximately 30%

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Laboratory Type:

- Hospital (private) 196
- Hospital (consolidated) 33
- Hospital (government) 21
- Public Health 18

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Laboratory Type (con't):

- Independent Reference 15
- Physician Office 3
- Clinic 3
- Other 3

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Primary Accreditation

■ AOA	1
■ CAP	204
■ CMS	25
■ COLA	2
■ JCAHO	47
■ Other	13

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Director Certification

■ ABB	207
■ ABCC	1
■ ABMM	12
■ NA	20
■ NBC	18
■ Other	21

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Academic Degree of QC Coordinator:

■ BS/BA	187
■ MS/MPH/MA	44
■ MD/DO	29
■ PhD	14
■ Other	12

Update on ASM Survey of Micro ID Systems

Number of cultures performed/year:

- < than or = to 5,000 cultures 43
- 5,001 - 10,000 cultures 52
- 10,001 - 50,000 cultures 140
- Greater than 50,000 cultures 53

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Number of Full Time Equivalents (FTEs):

■ Lab Associate	176
■ MLT	250
■ BS/BA	245
■ MT	1317
■ MA/MS	98
■ MD/DO/PhD	90
■ Other	16

Update on ASM Survey of Micro ID Systems

- Majority used 5 or more identification systems in their laboratories (range of 1-13 systems)
- Types of systems used:
 - Gram Positive (15)
 - Gram Negative (20)
 - Neisseria/Haemophilus (5)
 - Anaerobic bacteria (6)
 - Yeasts (6)

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- Total number of lots tested: 9886
- Total number of lot failures: 912
- Total number of lot replacements: 7

Update on ASM Survey of Micro ID Systems

Of those lots replaced:

- 3 lots had 1 failed test (2 Yeast, Anaerobic bacteria)
- 1 lot had 2 failed tests (Anaerobic bacteria)
- 2 lots had 3 failed tests (Gram Positive, Anaerobic bacteria)
- 1 lot had 6 failed tests (Gram Positive)

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Replacements by Micro ID System

<u>System</u>	<u>Total Lots Tested</u>	<u>Replaced</u>
■ Gram Positive	2672	< 1%
■ Gram Negative	4298	0
■ Neisseria/Haemophilus	898	0
■ Anaerobic bacteria	1014	< 1%
■ Yeasts	1004	< 1%

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Recommendation

- Request that the Clinical and Laboratory Standards Institute (CLSI) use its consensus process to determine the appropriate amount of QC based on survey data

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