

June 2015 CLSI QCWG

- » IQCP Ad Hoc Group Report
- » Tier 3 QC Review and Request for Data
- » Troubleshooting Guide Improvement Plans
- » Availability of Two Disk Manufacturers for M23 Tier 2 Studies
- » M23 Tier 2 Studies: 9 presentations, 43 ranges

CLSI QCWG

June 2015 Members (Will reassess members for 2016)

Member	Affiliation
Steven D. Brown, PhD, D(ABMM)	CMI (Retired), Co-Chairholder
Sharon K. Cullen, BS, RAC	Beckman Coulter, Co-Chairholder
Patricia S. Conville, MS, MT(ASCP)	FDA//CDRH/OIVD
Robert K. Flamm, PhD	JMI Laboratories
Stephen Hawser, PhD	IHMA
Janet A. Hindler, MCLS, MT(ASCP)	UCLA
Denise Holliday, MT(ASCP)	BD Diagnostic Systems
Michael D. Huband, PhD	JMI Laboratories
Jim Ross, MBA, MT (ASCP)	JMI Laboratories, Recording Secretary
Erika Matuschek - Absent	ESCMID, Clinical Microbiology Central Hospital
Ross Mulder, MT(ASCP)	BioMerieux, Inc.
Susan D. Munro, MT(ASCP), CLS	Independent Consultant
Robert P. Rennie, PhD	Provincial Laboratory for Public Health
Mary K. York, PhD, ABMM	MKY Microbiology Consulting

IQCP (Individualized Quality Control Plan) Ad Hoc Working Group Members

Susan Munro, Chair

Linda Bruno, ACL Labs, Recording Secretary

Mary Arndt, Beckman Coulter

Janet Hindler, UCLA

Susie Sharp, Kaiser

Maria Traczewski, Clinical Microbiology Institute

Barbara Robinson, ASM representative

Kathleen Todd, CMS representative

Penny Keller, CMS representative

Goals of Ad Hoc IQCP WG (Subgroup of QC WG)

Provide guidance to clinical microbiology laboratories:

1. Explain the new CMS requirements for an individualized quality control plan
2. How to create and implement an Individualized QC Plan (IQCP) using three components:
 - Risk assessment
 - QC Plan
 - QA
3. Determine the best process to disseminate information on IQCP

Accomplish by CMS deadline of Jan. 2016

Collaborative project with ASM and CAP

Completed AST IQCP

- Introduction
- Q & A
- IQCP for Commercial MIC system (PowerPoint)
- Example of IQCP for Commercial MIC system

Now posted on ASM Clinical Microbiology Portal

<https://clinmicro.asm.org/index.php/lab-management/laboratory-management/445-iqcp>

and CLSI Website (title needs tweaking- “Materials to help with CMS requirements”, prefer using acronym [IQCP](#), to help with potential searches)

<http://clsi.org/standards/micro/sub-ast>

Unfinished AST IQCP

Disk Diffusion IQCP

- ✓ Draft sent out to Ad Hoc WG members. Minor word-smithing at this meeting **Done**

New assignments—

- ✓ Exempt Media IQCP: **Reviewed and minor word-smithing at this meeting.**
- ✓ Commercial Identification Systems: To be accomplished by conference calls

Troubleshooting Guide

- » Valuable information for users to create IQCP and routine troubleshooting
- » Updates needed for both Disk and MIC
 - Incorporate comments from M2 and M7
 - Solicit inputs from AST Subcommittee
- » Volunteers requested to review and propose updates
 - Disk: Denise H and Erika M
 - MIC: Patti C. **Need additional volunteer**
- » Proposed Timeline
 - Draft for review/discussion in January 2016
 - Refine/approve in June 2016

Tier 3 QC Monitoring and Reassessment of Ranges

- » Data requests: AST Subcommittee, ASM Division C, Original M23 Tier 2 data from sponsors/study coordinator
 - Cefepime and *P. aeruginosa* ATCC 27853: Out high, Lab variability
 - Cefixime and *E. coli* ATCC 25922: Out low
 - Meropenem and *E. coli* ATCC 25922: Out high (5%)
 - Cefuroxime and *S. pneumoniae* ATCC 49619: Mode at low end of range (0.25) with one lab
- » Request inclusion of *K. pneumoniae* ATCC 700603 on Tier 2 Studies to establish additional disk ranges vs *E. coli* ATCC 35218
 - Must be used with avibactam combination drugs
 - Either *E. coli* ATCC 35218 or *K. pneumoniae* ATCC 700603 could be used for tazobactam combinations and other β lactamase inhibitor combinations
- » Notify Sharon Cullen if issues seen with other agents

M23 Tier 2 QC Studies

Two Disk Manufacturers Not Always Available

- » Tier 2 guidelines provide reasonable confidence with reasonable cost/time
 - Disks: Use of 2 different manufacturers (if possible)
 - MIC: Only one manufacturer required for panels
- » Tier 3 to confirm/adjust with additional experience
- » Past disk mfg variability infrequent
- » Proposal
 - Encourage pursuit of 2 disk manufacturers
 - If not available, add footnote “Range established with single manufacturer of disks.”
 - Refer to existing Tier 3 guidelines to refine ranges if needed.
 - Remove footnote when/if data from 2nd disk manufacturer is presented/accepted (process to be defined)