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Quality Management/ Checklist Updates

Information you need to know

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Quality Management

- **Microbiology must be included in the laboratories overall QM/QC plan (GEN.20100).**
- **QM program must include monitoring indicators of quality in the preanalytic, analytic, and postanalytic phases of testing. (GEN.20316).**

Examples:

- **Blood culture contamination**
- **Blood culture volume**
- **Specimen acceptability/rejection**
- **Critical value reporting**
- ***M. tuberculosis* susceptibility turn-around time**
- **Statistics for molecular infectious disease testing**

Quality Management – Specimen Assessment

- **Blood culture**
  - Volume (MIC.22640)
  - Collection techniques (MIC.22630) – tracking the contamination rate
- **Sputum**
  - Acceptability (MIC.22100) – also guide for work-up
  - Process for unacceptable (MIC.22110)
- **Wound cultures**
  - Criteria to determine acceptability for anaerobes (MIC.22675)
  - If acceptable, how to process for anaerobes (MIC.22700)

Specimen Collection - preanalytic

- **Collection devices and transport procedures must ensure sample integrity is preserved until sample is processed.**
- **Requests for testing must include specimen source.**
- **Collection and transportation instructions must be available to those submitting samples since most culture specimens are collected by others outside the lab.**

Scenario: Quality Management

While reviewing test results for blood cultures in a small community microbiology lab, you see that at least 6% are reported as “contaminated.” The bench technologist explains that the nursing staff is responsible for drawing the samples, and the lab has no authority over the nursing staff.

Evaluation: Quality Management

MIC.22630 Blood Culture Collection Phase II

Sterile techniques for drawing and handling of blood cultures are defined, made available to individuals responsible for specimen collection and practiced.

Evaluation: Quality Management

How would you respond to the previous checklist requirement?

A. **Cite a deficiency for an excessively high contamination rate.**
B. **Recommend nursing in-services.**
C. **Request more information.**
D. **Move on since the laboratory is not responsible for the high rate.**

Quality Improvement

- Use monitoring to improve your stress points
- Chose monitors that mean something
  - All monitors must have a benchmark or goal
  - All monitors must have a process for corrective action if the target or goal is not met

- Quality monitor for competency completion, all six elements, frequency?

Checklist Updates for 2018

Laboratory General, All Common, Microbiology

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2018 checklist edition changes – Summary* *Based on draft content – numbers not final*

Checklist	Requirements	New	Significant Changes	Deleted
ANP	200	15	28	0
BAP	171	1	5	0
CBG	83	0	3	0
CHM	165	13	6	4
COM	75	0	9	0
CYG	57	1	3	0
CYP	82	0	9	0
DRA	18	0	3	0
FDT	125	0	17	0
FLO	49	2	5	0
GEN	331	3	33	0
HEM	193	0	8	0
HSC	158	1	5	0
IMM	65	0	8	0
LSV	280	2	15	0
MIC	253	0	17	1
MOL	164	1	7	0
POC	56	0	1	0
RLM	115	0	21	0
TRM	257	1	33	1
URN	29	0	1	0
TOTAL	**2926**	**40**	**237**	**6**

2018 checklist edition changes

- **Director Assessment Checklist (previously Team Leader Assessment of Director & Quality Checklist)**
  - **TLC acronym changed to DRA, eg, TLC.10430 changed to DRA.10430.**
  - **TLC.10100 (Laboratory Director Qualifications) – Removed provisions for more stringent director qualifications for moderate complexity testing, PPM, and waived testing laboratories with test volumes exceeding 500,000 tests per year.**

2018 checklist edition changes

- **All Common Checklist**
  - **COM.01200 (Activity Menu) – Clarified that a laboratory must report all tests and activities performed under its CLIA number to the CAP, even if it's also accredited by another organization.**
  - **COM.10500 (Discontinued Policies and Procedures) – Revised the NOTE to state that discontinued procedures must be properly archived and be generally inaccessible to the working areas of the laboratory.**

2018 checklist edition changes

- **All Common Checklist**
  - **Test Method Validation/Verification**
    - **Created a separate section – Waived Test Implementation and moved existing requirement (COM.30980 Waived Test Implementation and Approval) into this section.**
    - **Combined separate sections for Test Method Validation/Verification, Method Performance specifications, and Reference Intervals into one section “Test Method Validation and Verification – Nonwaived Tests” for improved organization.**

2018 checklist edition changes

- **All Common Checklist:**
  - **COM.40850 (LDT and Class I ASR Reporting)**
    - **Renumbered from COM.40630**
    - **Combined Laboratory Developed Tests (LDT) and Analyte-Specific Reagent (ASR) reporting requirements**
      - **Added new content to address ASR disclaimer reporting**
      - **Removed ASR requirements from discipline-specific checklists (Cytogenetics, Anatomic Pathology, Flow Cytometry, Microbiology, and Molecular Pathology)**

2018 checklist edition changes

- **Laboratory General Checklist**
  - **GEN.59980 (Restricted Laboratory Access) – Added a new requirement for a policy for restricting access to the laboratory to authorized individuals to define:**
    - **How restricted access is maintained**
    - **Who is authorized**
    - **How temporary authorization is obtained**

2018 checklist edition changes

- **Laboratory General Checklist – Safety**
  - **Updated the liquid nitrogen (LN2) safety requirements (GEN.77500 & GEN.77550) to include use of:**
    - **LN2 environmental monitoring equipment (oxygen sensors and alarms for low oxygen levels)**
    - **Warning signage in areas where LN2 is used/stored**
    - **Training of staff on LN2 and dry ice handling.**
  - **Added requirement for formaldehyde and xylene monitoring (GEN.76720) – Removed from the Anatomic Pathology, Cytopathology, and Microbiology checklists.**

2018 checklist edition changes

- **Microbiology Checklist**
  - **MIC.11375 Taxonomy Changes –references**
    - **Added Journal of Clinical Microbiology References:**

Kraft CS, McAdam AJ, Carroll KC. A Rose by Any Other Name: Practical Updates on Microbial Nomenclature for Clinical Microbiology. J Clin Microbiol. 2017; 55(1):3-4.
Munson E, Carroll KC. What's in a Name? New Bacterial Species and Changes to Taxonomic Status from 2012 through 2015. J Clin Microbiol. 2017; 55(1):24-42. Erratum in: J Clin Microbiol. 2017; 55(5): 1595.
Simner PJ. Medical Parasitology Taxonomy Update: January 2012 to December 2015. J Clin Microbiol. 2017; 55(1):43-47.
Loeffelholz MJ, Fenwick BW. Taxonomic Changes and Additions for Human and Animal Viruses, 2012 to 2015. J Clin Microbiol. 2017; 55(1):48-52.
Warnock DW. Name Changes for Fungi of Medical Importance, 2012 to 2015. J Clin Microbiol. 2017; 55(1):53-59.

2018 checklist edition changes

- **Microbiology Checklist – MALDI-TOF**
  - **MIC.16595 Mass Spectrometer Calibration**
    - **A calibration control is performed during each run each day of patient testing, or with each change in target plate, or according to manufacturer's recommendations**

2018 checklist edition changes

- **Microbiology Checklist – MALDI-TOF**
  - **MIC.16605 – Mass Spectrometer Controls**
    - **Clarified that *appropriate controls include at least one representative organism for each class of organism tested (eg, a bacterium, a yeast, a filamentous fungi, an aerobic actinomycete, and a mycobacteria. For FDA-cleared/approved platforms, the organisms or calibrator(s) required by the manufacturer must be used.***

2018 checklist edition changes

- **Media QC – purchased**
  - **MIC.21240 – added to the note**
    - **Problems with media deterioration or loss of reactivity must be reported to the manufacturer with records retained as part of corrective action**

2018 checklist edition changes

- **Susceptibility testing – pure cultures**
  - **MIC.21820 – note revised for clarification**
    - **Purity plates must be performed**
    - **Purity plates must be done using non-selective media**

2018 checklist edition changes

- **Microbiology checklist – Parasitology**
  - **MIC.51170 Special Stain QC**
    - **Added Giemsa to the examples of special stains and clarified that laboratories may check stains used for blood parasites (eg, Giemsa, Wright-Giemsa) by confirming the intended reactivity of the stain on the cellular elements on the slide (eg, WBC, RBC, platelets). A slide prepared from a normal specimen can be used in lieu of a positive parasite slide.**

2018 checklist edition changes

- **Microbiology – Molecular Microbiology**
  - **MIC.65220 Multiplex QC**
    - **Note modified to account for the use of an IQCP if the test system has an internal control process**

Tools for transitioning to the 2018 edition

- **The following tools are available on cap.org after publication:**
  - **Changes Only Checklists : Each checklist can be downloaded in a “tracked changes” format highlighting changes between editions.**
  - **Deleted/Merged/Moved Requirements table: Tool helps to quickly identify changes in requirement numbers from one edition to another.**

Tools for transitioning to the 2018 edition

- **Checklist Update Webinars: Register to participate in the Focus on Compliance checklist update webinars:**
- **October 10 – 2018 CAP Accreditation Checklist Updates: Changes that Matter**
- **November 14th – What's New and What's Worth Revisiting in Anatomic and Cytopathology**

https://learn.cap.org/compliance.aspx

FAQs – What your colleagues are asking

Phone calls and emails

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Monthly QC and 20 day QC

- **Could you please tell me if the CAP requirement to perform monthly QC on test systems that contain and internal control is still current?**

- **I also believe that there was also a requirement to perform 20 day consecutive QC on these systems before putting them into use. If this requirement is still in effect (I was unable to find it on the 08212017 microbiology or all common checklist) would it apply to a waived molecular test that also has in internal control?**

Correlation studies

- I am helping a sister hospital's brand new supervisor perform her first self-inspection and we are debating one of the items. It is COM.04250 and COM.04300.
- Do these pertain to the MicroScan against Remel's RapID kits? For example, do we need to run Aeromonas and Pseudomonas on both the MicroScan and the RapID NF twice a year to fulfil this checklist item?

Correlation studies

- One of the facilities in our division has a MALDI and a Vitek. They both do identification (MALDI being the primary instrument), I am assuming that those do need to have instrument to instrument comparisons. Is this thought accurate?
-

Correlation studies

- **Our lab has a molecular instrument that has several modules that feed into the data analysis center. Do these modules have to be correlated to each other every six months?**

Comparability of Instruments and Methods

For Microbiology Testing, this requirement:

- **Applies when two instruments (same or different manufacturers) are used to detect the same analyte.**
- **Does not apply to multiple analytical methods (eg, antigen typing versus culture or detection of DNA versus a biochemical characteristic) designed to detect the same analyte.**
- **Must have acceptability criteria for the correlations**

Molecular Microbiology

Statistics:

- **When appropriate, statistics (eg, % of results that are positive for *C. trachomatis* and/or *N. gonorrhoeae)* are maintained and monitored. (MIC.63252)**
- **For quantitative assays, QC statistics are performed monthly to define analytic imprecision and to monitor trends over time. (MIC.65240)**
- **Turnaround time is monitored for appropriate tests. (MIC.63256)**

Statistics – when appropriate?

- **Percent positives monitored on monthly basis – good practice**
  - **Excess of positives – increase in false positives?**
  - **Decrease in positives - increase in false negatives? Loss of sensitivity?**
  - **Number of invalid tests or rejected tests**
- **Monitor statistics when moving from one methodology to another**
- **Benchmarks may be in literature but more often established by the lab**

Turnaround Time – Appropriate Tests

- **Clinical significance**
  - **Detection of HSV in CSF**
  - **Emerging pathogens**
- **Monitoring Disease**
  - **Viral Load studies**
- **Clinician/client requests**
  - **Approved by Laboratory Director**

Body Fluids - volume

- **MIC.22495**
  - **What is inadequate volume?**
  - **If using a broth, is centrifugation necessary?**
  - **If body fluids are inoculated into blood culture bottles – is it FDA approved? Has it been validated?**

If only plated media are used for sterile body fluids, fluid is centrifuged and the sediment used to inoculate media unless the entire specimen is plated.

NOTE: When inadequate volume is received, the report should note that the culture results may be compromised by the limited volume of specimen received. Equivalent methods are acceptable, if validated by the laboratory.

IQCP

- Do I need an IQCP on my catalase reagent, spot indole or PYR reagent?
- Do I need an IQCP on my blood culture media if I only draw the cultures but do not incubate or result them?
- Does the annual quality assessment of my IQCP need director approval?

Where did it go?

- **I can’t find this on my checklist, has it been deleted?**
  - **Check the list of deleted/ relocated requirements – deletion is rare**
  - **Check the lab’s activity menu**

Thank you!

- **Any questions?**

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References

- College of American Pathologists. *Laboratory Accreditation Manual*. Sharkey FE, ed. Northfield, IL: College of American Pathologists; 2017.
- College of American Pathologists. *Microbiology Checklist.* Northfield, IL; College of American Pathologists; 2018.
- College of American Pathologists. *Standards for Accreditation.* Northfield, IL: College American Pathologists; 2013.