A slimmer molecular micro section among changes to checklists

Anne Paxton

August 2017—There was no trip to the spa. But some sections of the 2017 edition of the CAP Laboratory Accreditation Program checklist are looking trimmed and toned compared with last year's checklists. A microbiology section that is shorter by eight pages, fewer Individualized Quality Control Plan reporting requirements, and a new section addressing chain of custody once again reflect the hard work of the Checklists Committee and scientific resource committees to achieve conciseness and clarity.

Additional checklist changes

Molecular microbiology is one part of the checklist that is noticeably slimmer and lighter than last year's model; the section is now only about two-thirds its previous length. "This is by far the biggest revamp we've done of the microbiology checklist," says D. Jane Hata, PhD, D(ABMM), a member of the Microbiology Resource Committee (MRC). "Concerns about individual checklist requirements certainly come up at every MRC meeting, but I think this was a much bigger project."

Dr. Procop

The requirements themselves were refined very little. Instead, the formerly separate sections for FDA-approved or -cleared, modified FDA-approved or -cleared, and laboratory-developed tests have been combined into one. "This was largely an extensive reorganization and clarification initiative," says Gary W. Procop, MD, MS, medical director of molecular microbiology, virology, mycology, and parasitology labs at Cleveland Clinic and past chair of and now advisor to the MRC. Other items that were already in the all common checklist were removed, while the number of requirements in the molecular section of the microbiology checklist was reduced from 71 to 56 because of all the combinations that were made.

Feedback to the accreditation program spurred this consolidation. "Participants reported that the former version of the checklist, particularly the molecular microbiology portion, was confusing. Some participants were unsure which of the sections to use, given the various subdivisions, and there were several duplications between the various sections," Dr. Procop says. "The subspecialty experts of the MRC worked to clarify and label each part of the checklist, so that users would clearly understand which sections were applicable to their tests. Duplicative information was consolidated, whenever possible."

The reorganized checklist now includes subsections for electrophoresis, microbial in situ hybridization, and sequencing.

The Microbiology Resource Committee believes laboratories will find the revised checklist clearer and more user-friendly. "The essence of the requirements hasn't really changed," says Susan E. Sharp, PhD, D(ABMM), a member of the MRC and director of microbiology, Kaiser Permanente Northwest Region Laboratory. "We basically have just reorganized and eliminated redundancy. Regardless of the type of testing you're doing, you have had to perform validation and verification studies, so why not bring everything together?"

The change doesn't affect the inspection process, Dr. Sharp adds. "But it will make it easier for laboratories to know they are in compliance."

As a result of the consolidation project, the committee opted to remove a chart that had appeared at the front of the microbiology section and was meant to be helpful, but was not. "Laboratories had difficulty interpreting the chart. They were confused when tests they were performing were not listed, and they didn't know which part of the checklist to use for that particular test. Once we reorganized the checklist, the chart was found to be unnecessary and was eliminated," Dr. Sharp says.

Dr. Sharp

Other changes were more minor. For example, the MRC agreed to replace the term "sample" with "specimen" in the assay validation and verification section (MIC.64770). "This requirement specifically refers to when you are going to use a specimen that is different from the specimen type cleared by the FDA. It just seems more clear to refer to these as specimens rather than as samples," Dr. Sharp explains.

"There are still several checklist requirements for assay validation and verification in the microbiology section. Part of these requirements indicate you need to have records showing that the appropriate validation and verification studies were done," she notes. The all common checklist also contains further information on validation and verification testing.

To make the language more consistent in MIC.65140 and other checklist requirements, the MRC changed the term "non-FDA-cleared/approved test" to "laboratory-developed test." "They're really the same thing, so we are trying to label them the same way," says Dr. Hata, director of clinical microbiology and serology labs at Mayo Clinic in Florida.

The small but significant word "written," pertaining to criteria for calibration verification, was added to MIC.65150. "When you walk into a lab, the lab might say, 'Well, yes, of course we do this.' But without written documentation it's very difficult to justify a finding that best practices are being followed," Dr. Hata notes.

Few changes were made in the instruments section of the molecular microbiology checklist. "These testing methods change rapidly, and we went through these specific requirements to make sure they were technologically accurate," Dr. Hata says. Most were found to be fine and needed no change. But MIC.65580, Group B Screening, was clarified to note that it relates to screening done by non-amplified DNA probe. "There are specific tests for Group B that use non-amplified technology, and they don't fit neatly into one of the categories we've delineated in this section, so we wanted to set that off" from MIC.65590 (Group B Screening-Amplified Method).
In the results reporting section, the MRC opted to change "ASR Report" (in MIC.66120) to "ASR Disclaimer" to employ current terminology. "We know the definition of ASR [analyte-specific reagent] is continually changing, and I'll say in advance that we'll probably be changing this again as the definition changes. These checklists are always in flux," Dr. Hata says.

New language in MIC.66120 also adds that "The laboratory may put a single ASR disclaimer on the patient report for all microbiology studies collectively used in a particular case. Separately tracking each reagent used for a case and selectively applying the disclaimer to only the class I ASRs is unnecessary." This change will lighten laboratories' reporting, Dr. Hata explains. "Some labs would put four or five instances of this particular disclaimer on a single patient report, making it messy and difficult to read. We were trying to help labs by indicating you only

need to do it once."

Dr. Hata

Particularly in this round of changes, the MRC has often sought to follow the concept of less is more. But, as Dr. Hata suggests, "less" is not always easier to achieve. "As these checklists evolve, it's easy to add items, especially when it becomes apparent specific needs should be addressed. Granted, it can be more work to go back and clean up redundancies, but it is necessary."

Checklist changes can sometimes be unnerving for laboratories, Dr. Hata admits, but she believes once labs read through the revised molecular microbiology requirements, they will find the items to be much clearer. The committee counts on accreditation program participants to help with the process, she says. "We have a very smart membership. They bring up valid points, and I think it's always good to continually go back and review these checklists to make sure they're doing what we need them to do."

In the all common checklist's section on Individualized Quality Control Plans, the Checklists Committee made mostly housekeeping changes rather than anything sweeping, says Accreditation Committee member Deborah Perry, MD, a past chair of the Point-of-Care Testing Committee and medical director of pathology at Methodist and Children's hospitals in Omaha, Neb. "There are some good updates now that we've had time to use the checklist and develop IQCP."

The biggest change is that there will only be one form to complete because the committee eliminated the IQCP summary form. In 2016, the CAP implemented two different forms, explains William W. West, MD, of Physicians Laboratory Services, Omaha, Neb., and chair of the Checklists Committee. "One was an IQCP list of the IQCPs you had in the lab; the other was a summary form that asked for details on how you set up IQCPs in the first place. People said on the summary form that they were often just listing what was already on the IQCP documentation in the lab itself; it was duplicative. As we looked at it, we thought we could eliminate the summary form by including a few other details on the list form. So we cut the number of forms from two to one by doing that."

Dr. Perry

Under COM.50200 in the 2017 checklist, labs need only have the IQCP list form ready for the inspection team's review when inspectors are on site. Since the Centers for Medicare and Medicaid Services does not require the use of specific forms, clearance from the CMS was unnecessary. "It was an ease-of-operations change that is effective immediately," Dr. Perry says.

This change, in fact, was already announced with an e-alert from the CAP on May 17 and took effect right away. "Some labs already had both forms filled out because they were using the electronic versions available from the College at that time," Dr. West says. "The e-alert said you no longer have to fill out the summary form, but if

you've already completed both forms, they're still good. In the next inspection cycle you're not going to be dinged. But from that point on, just the IQCP list form will be available on the College's website."

As of mid-August, the information previously requested on the IQCP summary form for processes to control risk is no longer included on a CAP form; inspectors are instructed to review the laboratory's risk assessment and quality control plan for this information. Laboratories will still need to do risk assessment, Dr. West emphasizes. "That's still a very important part of an IQCP and inspectors will look at their documentation, but they no longer have to put that on a separate form."

The other IQCP change due to have the most impact is the removal from COM.50500 the requirement that external QC be performed every 31 days, Dr. Perry says. That update has been considered ever since IQCP was introduced two years ago—"partially because a lot of the IQCPs are used for point-of-care devices. Thirty-one days is a bit limiting with some of the point-of-care tests."

The prospect of cost savings was part of the motivation here. "Labs were using a lot of QC material on POC devices that don't analytically probably need it. And the fact that most POC tests have a cartridge, and much testing is done internally, means you probably don't need as much external QC as years ago," Dr. Perry says.

Two years of using IQCP, she adds, have helped people see that the data support a potentially longer interval between external QCs. "People are able to document that, yes, using it every 31 days has shown we could safely extend it and have no compromise in the quality of the testing." The time interval would still vary based on the laboratories' risk assessments, so some will make the time interval 35 days, or 45 days. "But there is still the requirement that you can't do it less frequently than the manufacturers' instructions. If the manufacturer mandates 28 days, you can't go less than that."

Dr. West

Compiling historical data is one of the five elements required for laboratories' risk assessment, in addition to following manufacturers' instructions. Under the changed COM.50300, laboratories must include their own lab-specific data to show that performance is acceptable. "If you're saying you only need to run external QC at a certain frequency, basically you need to show that the testing in your lab is stable enough to allow that extended frequency," Dr. West says. "If you're saying you only have to run external QC once every two weeks but you only have five days' worth of data, that doesn't show that the test is stable for a two-week period."

A new section makes its debut with this edition of the laboratory general checklist: chain-of-custody specimen collection and handling, which is intended to ensure that laboratories have good documentation when legal or forensic testing specimens change hands. The chain-of-custody checklist requirements were originally in the legal testing section of the chemistry and toxicology checklist. That section was created for in-house blood alcohol testing, says Richard M. Scanlan, MD, chair of the Commission on Laboratory Accreditation and a professor and vice chair of laboratory medicine, OHSU School of Medicine. "We moved the chain-of-custody checklist items out of the chemistry checklist and put them into a laboratory general section so they wouldn't be tied to testing."

This move originated with a proposal to eliminate the entire legal testing section in the chemistry and toxicology checklist. Every year, the CAP's scientific resource committees are asked to look at the checklist content appropriate to their expertise, Dr. West says. This year, the Toxicology Resource Committee said the legal testing section of the chemistry and toxicology checklist was a problem because in essence it suggested that labs can do

limited forensic testing without going through the full Forensic Drug Testing Accreditation Program. But feedback from laboratories was clear: “They needed something for specimen handling in potential legal cases,” Dr. West says. The Commission on Laboratory Accreditation suggested the needed requirements be added to the laboratory general checklist.

The new section is aimed not at labs that perform the testing in-house, but at those that collect samples to be tested by other labs for legal purposes. It “defines how the lab maintains the chain of custody from the patient’s arm to the laboratory that’s going to test it,” Dr. Scanlan says. “Legal samples have to be under very tight control, and the additional requirements are things that might draw legal criticism if they weren’t followed to the letter of the law.” Such items include keeping records as needed for pending legal action, securing specimens while they are in the laboratory, who can touch specimens, and where they can be kept.

Dr. Scanlan

There are six new requirements related to the use of a chain-of-custody process. “The crucial thing is to have a policy for how to handle these samples until they get to the lab ultimately doing the testing, typically a toxicology lab. The testing lab may define its own chain-of-custody procedures, and the originating lab needs to follow that protocol,” Dr. Scanlan says.

Labs that aren’t doing legal testing under their scope of service—that would be the majority of labs—won’t see these requirements. Labs that check off the activity for chain-of-custody collection (No. 6468) for services such as pre-employment testing and workplace drug testing will see the requirements. “If they tell us they’re doing this work in their activity menu, that will prompt the six requirements to show up on their checklist. We’ve tried to keep the requirements under control. So when an inspector comes through, they’ll know to look for those things even if the lab is not doing in-house legal testing.”

The overlap between Laboratory Accreditation and the Forensic Drug Testing (FDT) programs generated extensive discussion, Dr. Scanlan says. “The legal section was originally put in years ago for blood alcohol; then people were using it for other forensic testing like drug screening for cause. And it just got to be too concerning. It was being handled as ‘FDT Lite’ and it was a little too ‘lite’ to be viable. We want people doing on-site forensic drug testing to be in the FDT program.”

Most labs are not going to move to an FDT program, Dr. West believes. “I don’t think very many small facilities that just do an occasional specimen will have an interest in becoming FDT-accredited, so they will have to decide what testing they want to do. It wouldn’t make a lot of sense for the smaller facilities to become FDT-accredited because it adds significant expense. However, the new chain-of-custody section will help them understand how they have to handle specimens for potential legal testing or forensic testing to ensure the handling is sufficient for those purposes.”
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