First IQCP template set up for molecular tests

4 microbiology templates revised

Valerie Neff Newitt

April 2022—Drawing on five years of experience and laboratory feedback, a collaborative team has revised the microbiology IQCP templates and created the first template for the quality control of a commercial cartridge-based molecular test system.

“The original [microbiology] templates are perfectly acceptable, and laboratories comfortable with using them can continue to do so,” says Elizabeth Palavecino, MD, professor of pathology and director of the clinical microbiology laboratory, Atrium Health Wake Forest Baptist Medical Center, and director of the Forsyth County Laboratory of Public Health, Winston-Salem, NC.

The new molecular testing template “is something people want and need,” she adds, noting the need became greater during the pandemic when reagents were in short supply. With an individualized quality control plan, “If your risk assessment is good, you can maybe use less QC,” she explains.

The format of the new molecular testing template will be familiar to users of other IQCP templates. “We wanted to use the same format so it would not seem too foreign, too different, too complicated,” says Dr. Palavecino, a member of a joint group of the CAP, American Society for Microbiology, and Clinical and Laboratory Standards Institute that developed the new template and revised the microbiology templates.

“It’s been five years since the templates were first introduced,” and the feedback has been positive, says Laura Filkins, PhD, D(ABMM), a member of the group and assistant professor of pathology at UT Southwestern and clinical microbiology laboratory director, Children’s Health, Dallas. “We didn’t change anything problematic or critical. We didn’t undo anything. Rather our effort was more a matter of embellishing the templates to make them even more user-friendly.”

The revised IQCP templates are for minimal inhibitory concentration-based antimicrobial susceptibility testing, disk diffusion AST, streamlined QC of a commercial identification system, and commercially prepared “CLSI-exempt” media. All are online at https://asm.org/protocols/individualized-quality-control-plan-IQCP.

Sheldon Campbell, MD, PhD, professor of laboratory medicine, Yale School of Medicine, and associate chief of laboratory medicine at VA Connecticut Healthcare, and also a group member, says IQCPs ushered in a more comprehensive approach to the quality management of tests. “These templates are designed to give laboratories as much guidance as possible on how to do risk assessments, what to include, what things to think about for the different types of tests as they prepare to write up their individualized quality control plan.”

Dr. Campbell

In the “Ebola era,” he says, he had no idea how to do a risk assessment. “Those of us who bushwhacked through the wilderness are trying to send a map back to the folks who are getting ready to do the same. IQCPs have made us all come up to speed.”

During the pandemic, Dr. Campbell says, “more and more labs are bringing on molecular tests at a ferocious rate.

They're being put into labs that have never done molecular testing before." For those labs, he says, "we tried to be as comprehensive as possible in our listing of areas where labs could look for risk and create examples of how to look for it." Laboratories that already have an IQCP can use the new template to compare and to ask if they've left anything out or if they can "steal" any good ideas, he says, adding, "I'm all about stealing good ideas myself."

There is a lot to consider when developing an IQCP for any test, Dr. Campbell says, but introducing a new molecular test brings with it additional considerations. "For example, contamination risks can be overlooked because that's relatively unique to molecular test systems," he says. "And there are things that result not necessarily in inaccuracy but in delays. Delayed reporting is something people sometimes do not think about in their risk assessment, but delayed testing can have clinical consequences too." Without the type of guidance the template provides, he says, it would be easy to leave out important items.

Dr. Filkins

Dr. Filkins cautions that the template is not one-size-fits-all. "We highly recommend that laboratories modify the templates according to the tests they are running and their own environment, but the template offers a starting point and strong guidance."

The microbiology IQCP templates and the new QC of Molecular Test System template begin with the five main areas of information needed to conduct risk assessment: regulatory and accreditation requirements, testing personnel, specimen, environment, and test system and reagents. "The major change we provided in the revisions is the inclusion of examples of the type of related data laboratories should collect for each of the five major sources of risk," Dr. Filkins says.

Some things that were scattered throughout the original templates are now organized in the five subsections, which coordinate with a lab's standard operating procedure. So it's clear what information the laboratory needs to get and under what SOP the lab could find the information. "It goes with the flow of the lab, and I think that's important," Dr. Palavecino says.

Though the risk assessment is required, Dr. Filkins says, laboratories need not show within the IQCP what data they used to perform the assessment. "Data collection has to be performed, you do have to do it, but you don't have to keep it in the same IQCP document." The introductory page on all of the templates provides examples of metrics a laboratory can consider using when performing risk assessment. "Laboratories don't have to pull the exact documents we are recommending," Dr. Filkins says, "but they should be doing something equivalent that makes sense for their laboratories."

Among the many questions laboratory staff have about IQCPs, the question Dr. Campbell hears most often is, What constitutes a test system? "That is still complicated for a lot of module-based test systems," he says. "You've got a central computer connected to eight modules, each of which does a cartridge-based molecular test. How many test systems is that? Defining a test system turns out to be fairly complicated, and I'm not sure we have a complete answer. But one important point is that a test system includes not just the box and hardware, but the reagents, the software, the connection to the laboratory and electronic health records—all those kinds of things."

Dr. Palavecino

Another question he hears often: Will IQCP reduce the amount of QC testing that I have to perform with my laboratory testing?

On this they have become explicit, he says, about what the point of an IQCP is. “The IQCP is there so you don’t have to do daily QC. If you want to do daily QC, you don’t need an IQCP. So this may relieve labs a little, and we’re being explicit about it.”

For Dr. Palavecino, the question she gets most commonly is: We have three identical instruments in our laboratory. Can we do a single IQCP for all three?

“That’s an old question, but still I get it a lot,” she says. “I tell people if they have three instruments in the same location, it is okay to do a risk assessment once and include the three instruments. But if the instrument is in another hospital, even though they’re in the same system, they have to do their own risk assessments.”

Dr. Campbell too fields the same question. “If you have multiple identical instruments in the same location, you don’t need a separate IQCP for each one,” he agrees. “But the same instruments in different locations have different risks, due to physical location, personnel involved, different patient populations. For example, if you have an instrument that’s located in your pediatric emergency room satellite lab and one in your cancer center satellite lab, there may well be differences in risk assessment for both because children are different from adult cancer patients.”

How often the IQCP needs to be reviewed and revised is the question Dr. Filkins gets most often. “Our CAP checklist defines how often you have to reapprove an IQCP, so I think most labs are familiar with that component,” she says. “However it’s not always at the forefront of people’s minds that when there’s a failure or an indication of failure at any point in the process, they have to troubleshoot and try to find the source of the error.

“When they make the conclusion about a source of error,” Dr. Filkins continues, “they should go back and reassess their risk assessment and risk assignment, and determine—now with new information—whether they are comfortable with what happened. Do they understand the source of risk that occurred and has it been fixed, and is it unlikely to happen again? Is this an indicator that their instrument is getting old or their QC material is not as stable as they thought? Is there something that would change their perspective on what that level of risk is and that they therefore would want to include in their quality control plan?”

“Maybe they want to increase the frequency of their external quality control testing,” she says. “Perhaps there is something additional they would want to include in their quality assessment—the third component of the IQCP.” When there’s a major failure, she adds, laboratorians should reassess their IQCP as a whole and determine if it needs to be changed, revised, and reapproved.

A two-year IQCP review is an opportunity to make sure it’s up to date, she says. “As a laboratory director, when I sit down to review our protocols or our IQCP, I always have had different experiences in those past couple of years that might trigger something, where I say, ‘Oh, I didn’t realize it was written this way,’ or ‘We now have this other report that we evaluate every year and we should be including that.’”

Dr. Palavecino shares an incident in her laboratory when she, too, realized she needed to review her IQCP. “My QC failed and continued failing for three days. My original IQCP included documentation that showed no QC failures for this system. I had to review my IQCP and do a new risk assessment to figure out why I was getting failures with my QC for one particular organism-antibiotic combination.” They found the cause: A change to the air-conditioning

system caused one of the vents to blow cold air on top of the instrument and lowered the temperature in the instrument. Blocking the vent was an easy fix. “This highlights that changes in environmental conditions can modify the original risk assessment results and require risk reassessment,” Dr. Palavecino says.

“We need to pay attention to everything. It’s not only the reagents, the organisms, and the instrument, but the outside environment as well. Everything plays a role.”

What minimum frequency of QC testing is allowed when using an IQCP is another oft-asked question, Dr. Filkins says, “because the answer to the question is not prescriptive and not one-rule-fits-all-labs. It depends on the testing method you’re using.” Some accrediting agencies do have a minimum. “The CAP, for example, has a minimum frequency of QC that’s required for antimicrobial susceptibility testing. Even though CLIA and the IQCP rules do not specify, the CAP does. If your accrediting agency has a minimum, then clearly you need to at least cover that minimum.” Laboratories also need to meet the minimum that the manufacturer requires, she adds. “And beyond that, the minimum amount should be determined based on your findings within your IQCP. What is your risk level, and what role would external quality control testing play in helping you to assess if there are errors?”

Drs. Campbell, Filkins, and Palavecino hope their efforts and the resulting new and revised templates will provide labs with as many examples of risks—and the data needed to find and correct related errors—as possible. Says Dr. Campbell: “In the revisions we made incremental changes and came up with things that maybe were missing or unclear. We spent a lot of time trying to clarify language and make particular examples that would be exemplary and useful to people.”

The essence of the IQCP, Dr. Filkins says, is to help achieve the highest quality of testing by recognizing all sources of potential error. “The update of these templates provides a great opportunity for lab directors and designees to assess their current IQCP processes and determine if there’s room for enhancement, improvement, clarification, or adjustments. These templates do not suggest that you have to adopt them or that there’s anything wrong with the prior versions,” she says. But they are a good opportunity for a laboratory to reflect on its existing processes, she adds, and determine if improvements can be made.

Valerie Neff Newitt is a writer in Audubon, Pa.