HIV, TB requirements in latest accreditation checklist edition

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June 2020—Best practices for HIV primary diagnostic testing and rapid detection of *Mycobacterium tuberculosis* complex are clarified and codified in new checklist requirements in the 2020 Laboratory Accreditation Program checklist edition published June 4.

A new requirement pertaining to blood culture contamination and a revised TB exposure plan requirement are also in the new edition.

CHM.33790 "HIV Primary Diagnostic Testing—Supplemental and Confirmatory Testing" is a new requirement initiated by the CAP Microbiology Committee and added to the chemistry and toxicology, immunology, point-of-care testing, limited services, and microbiology checklists.

It calls for the laboratory to follow public health recommendations or guidelines for HIV primary diagnostic testing, including primary screening and additional (supplemental and/or confirmatory) testing. The note says if additional testing after a primary screening test is recommended by public health authorities, the laboratory should perform additional testing reflexively if the specimen is suitable and the test is performed in-house, or send additional testing to a referral laboratory if the specimen is suitable, or provide guidance to providers about submitting additional specimens, if needed for supplemental or confirmatory testing.

Dr. Rhoads

The recommendations are to do two tests, the screening test and a confirmation test, says Daniel D. Rhoads, MD, D(ABMM), a member of the Microbiology Committee and section head of microbiology at the Cleveland Clinic. "However, we did not explicitly require that labs handle it in one specific way. The goal of the checklist is to make it easier for clinicians and patients to get the whole answer without doing more blood draws or getting incomplete results."

He and others saw it as a gap in the checklist. "The requirement helps to put results in context, and helps providers and patients get the whole answer instead of just the first step in an algorithm. It is good lab medicine."

"HIV testing has always been a two-stage process, sometimes more," says Sheldon Campbell, MD, PhD, a member of the CAP Checklists Committee and professor of laboratory medicine at Yale School of Medicine and pathologist, VA Connecticut Healthcare System. "Basically we said laboratories are part of this process of getting supplemental or confirmatory testing, when required in HIV testing algorithms. Although we never required it in the checklist before, it has already been practiced since the very early stages of HIV testing."

As the testing algorithms become more complex, the CAP decided this was the right time to raise awareness and have laboratories help providers navigate the algorithms more systematically, Dr. Campbell says.

"Because these algorithms have gotten so complicated, sometimes you can do reflex testing on the same specimen, and sometimes you have to get a new specimen," he says. "Sometimes labs have the supplemental testing in-house, and sometimes they don't. These complications can be challenging for providers to negotiate

because there are so many options. Labs are in a better position than providers to make that call because they know where the testing is being performed and what specimens are needed."

Dr. Campbell

The new requirement consolidates testing whenever possible. "As laboratory directors and as laboratories, we should always be looking for ways to provide a total answer," Dr. Rhoads says. "It's best to link tests so that a more complete answer can be provided to the person asking for the test and to the patient. There are times when it is good practice and can be helpful, but this is one time where we see it as essential."

For all the benefits the requirement affords, it has the potential to put more burden on smaller labs, he says. "Big laboratories can do the screen and the confirmation in-house and make that routine—no big deal. However, it might be challenging for a smaller lab that only does the screen and doesn't have confirmation testing. While they do not have to do it in their own lab, they do need to help the clinician get that specimen sent to a laboratory that can do the confirmation."

"Certainly it is easier," Dr. Campbell says, "to just do the test that's ordered and be done with it. Now laboratories are required to be more active participants in the whole cycle of testing, from preanalytical to postanalytical phases."

The evidence of compliance is a written policy for the performance of HIV testing, Dr. Campbell says, "including what to do with negatives, what to do with positives, how to report them, what additional testing you need to perform or send out, comments or requests for further testing on the part of the provider in the case of things that require such, and then patient reports with those results and guidance."

Two new related requirements, both aimed at promoting rapid detection of TB, are in the newly released microbiology checklist. The first, MIC.32150 "Rapid Detection of *Mycobacterium tuberculosis* Complex—Laboratories Subject to US Regulations," is based on World Health Organization and Centers for Disease Control and Prevention guidelines.

The second, MIC.32170 "Rapid Detection of *Mycobacterium tuberculosis* Complex—Laboratories Not Subject to US Regulations," allows laboratories to follow the established algorithms of their home countries or regions. Both requirements apply to patients suspected of having pulmonary tuberculosis, and do not apply to all situations in which a mycobacteriology culture is ordered. If TB is not suspected and testing is performed for reasons other than ruling out pulmonary TB, the requirement is not applicable.

"We try to be judicious about what we add to the checklist," Dr. Campbell says of the decision to add the new TB-related requirements. But guidance on TB "was starting to become unanimous and overwhelming. Roughly a third of the population in the world is infected with *Mycobacterium tuberculosis*. Granted, most are latent, asymptomatic cases." But WHO reports 10 million new TB cases a year, he says, and 1.6 million deaths a year as of 2017. "It's still a tremendously important infectious disease health problem. We decided rapid detection of TB has reached the standard of having to be included in the checklist."

Neil W. Anderson, MD, D(ABMM), a member of the Microbiology Committee and assistant medical director of microbiology at Barnes-Jewish Hospital and assistant professor, pathology and immunology, Washington University School of Medicine in St. Louis, says the requirement "is talking about testing for active tuberculosis infection, different than latent TB. That needs to be very clear."

MIC.32150, for laboratories subject to U.S. regulations, requires that a nucleic acid amplification test be available, in the laboratory or by a referral laboratory, for the rapid detection of *Mycobacterium tuberculosis* complex on at least one respiratory specimen submitted to the laboratory (preferably the first diagnostic specimen) for mycobacterial culture.

It also notes: The CDC and WHO algorithms for diagnosis of *Mycobacterium tuberculosis* complex infections recommend performing a diagnostic nucleic acid amplification test (NAAT) on the initial respiratory specimen from patients suspected of pulmonary tuberculosis. This can include physician requests for patients with signs and symptoms of pulmonary TB for whom a diagnosis of TB is being considered but has not yet been established, and for whom the test result would alter case management or TB control activities (high index of clinical suspicion).

“This is a very delicate item. We don’t want people to misinterpret this,” Dr. Anderson cautions. “It’s an example of the CAP trying to promote best practices. WHO and the CDC recommended the availability of molecular testing because the diagnosis of active TB is time-sensitive. Molecular methods allow for a more rapid diagnosis than culture-based methods. You can diagnose and treat faster, and potentially help stop the spread of TB, through this requirement. However, we were very careful in how it is worded. The final wording of the checklist requirement says the testing is ‘available.’”

Dr. Anderson

Dr. Anderson explains: “We have specified that testing be ‘available’ so that all laboratories can adopt this as a best practice without having to institute molecular testing, which would require levels of expertise and instrumentation that not every lab has access to. ‘Available’ means labs may either perform the testing on site or have a system set up so they can send it to a reference lab. One might argue that sending to a reference lab could diminish the turnaround-time benefit. But sending to a reference lab for molecular testing will still be quicker than growing a *Mycobacterium tuberculosis*. Culture still has great sensitivity, but this is all about getting an answer quicker and being able to make a positive impact by preventing spread. It’s all about speed.”

In no way, he says, should this lead to labs no longer doing mycobacterial testing because they can’t do PCR in-house. “That is not the intention here. We don’t want to limit anyone’s practice; we want to expand it when possible.”

Dr. Campbell, too, says the requirement was written so as not to be “draconian but to encourage laboratories to be part of the solution, not to be just a pass-through for providers.”

The CAP’s position on avoiding overuse of NAAT is part of the equation, Dr. Anderson says. “PCR is very, very expensive. There are laboratories, particularly in the U.S., performing a lot of cultures for mycobacteria, for more than just tuberculosis. For instance, a laboratory may end up having 30 of these cultures in a single day, and the vast majority might be from patients who have other mycobacterial infections and for whom tuberculosis is very low in the differential. If we were to require a laboratory to run PCR on every single specimen that came through, it would be a huge waste of resources.”

The required evidence of compliance for U.S.-regulated labs is a written policy for availability of *M. tuberculosis* complex NAAT and patient reports/worksheets with NAAT results or referral laboratory reports with results.

“Some labs might not have a written policy for availability of testing yet,” Dr. Anderson says. “But this could be as simple as a lab making this available on its test menu based on send-out tests and having a policy that allows for physicians to order NAAT when it’s clinically desired.” He poses a possible question inspectors might ask

laboratories: “If a physician suspects tuberculosis in a patient, how would they go about getting molecular testing and what are the policies in place for molecular testing?”

“That’s the way I’d ask it on an inspection,” Dr. Anderson says.

MIC.32170 “Rapid Detection of *Mycobacterium tuberculosis* Complex—Laboratories Not Subject to US Regulations” differs from MIC.32150 in that it provides more flexibility. It says appropriate testing is available, in the laboratory or by referral laboratory, for the rapid detection of *Mycobacterium tuberculosis* complex on at least one respiratory specimen submitted to the laboratory (preferably the first diagnostic specimen) for mycobacterial culture that includes a nucleic acid amplification test or follows an established testing algorithm for that country or region.

Bharati Suketu Jhaveri, MD, immediate past chair of the CAP Council on Accreditation and a member now of the CAP International Accreditation Committee, has inspected many international labs and has extensive experience in helping to create requirements suited to international laboratories. Although best practices are clear here in the U.S., she says, barriers exist for some labs in other countries. “If we make our best practices a requirement for laboratories that do not have access to high-end molecular tests, they would not be able to be in compliance and could not be accredited,” explains Dr. Jhaveri.

‘If all these laboratories had to send specimens to referral laboratories for NAATs, it could be a prohibitive expense.’
Bharati Suketu Jhaveri, MD

Having consulted with TB experts in the laboratory field, particularly in India where TB is endemic, Dr. Jhaveri says she learned they wanted the CAP to permit each country to work with its own health commissioner and health department, have access to guidelines that each country can use in its own hospitals, and use that country’s own algorithms and best practices. “So the checklist requirement stipulates labs follow the guidelines they are subject to in their region for patients suspected of having pulmonary TB,” she says. “Again, it is aimed at rapid detection. So with the first diagnostic specimen, labs preferably will do a nucleic acid amplification test or follow an established testing algorithm for that country or region.”

Dr. Jhaveri says algorithms do not vary widely from country to country because they are largely based on WHO guidelines. “However, labs in these countries have worked for years to find the best testing for them in their own environment and to utilize what is widely available and inexpensive. If all these laboratories had to send specimens to referral laboratories for NAATs, it could be a prohibitive expense to people who cannot even afford their medication.”

There is also disease prevalence to consider, Dr. Anderson says. “In some areas of the world where there is a lot of tuberculosis, the pretest probability is very high” and the benefit of PCR testing is lower. “If the physician is

convinced that a patient has tuberculosis and is in a region where TB prevalence is high, it makes more sense to assume the patient has TB and treat. While the requirement says it might be a good idea to offer nucleic acid amplification testing, by allowing laboratories to alternatively choose to follow an established testing algorithm for that locale, we're giving them an out. This flexibility makes the requirement more portable to other countries around the globe."

Dr. Campbell advises international labs to drill down on the public health record requirements in their regions and to be responsive to them. He says labs will need to be able to tell inspectors what the policy, which may or may not involve a PCR test, is. They will have to maintain documentation of that policy and have records to show it is being adhered to.

Two other checklist requirements, one revised and one new, address TB exposure and blood culture contamination.

GEN.74900 "Tuberculosis Exposure Plan" addresses employee screening and safety. This revised requirement says, in part: The laboratory follows a written tuberculosis exposure control plan that includes TB exposure screening at defined intervals for all personnel who have occupational exposure to tuberculosis, and use of engineering and practice controls for hazardous activities that may potentially aerosolize *Mycobacterium tuberculosis.*

The plan must define when exposure screening will be performed and who may have occupational exposure to tuberculosis.

Dr. Campbell says the requirement, though now more specific about what must be included in a laboratory's exposure control plan and about exposure screening intervals, also allows labs greater flexibility in terms of how often they test personnel. "The newest TB exposure recommendations from the CDC allow facilities with a very low incidence of tuberculosis to decrease the frequency. So people don't have to get tested every year for latent tuberculosis when their risk is very low and when the risk of a false-positive test starts to generate problems in terms of excessive follow-up testing," he says.

MIC.22635 "Blood Culture Contamination" is a new requirement in the microbiology checklist. It is largely broken out of an existing requirement and has been changed from a best practice activity to a requirement.

The requirement calls for the laboratory to monitor blood culture contamination rates and establish an acceptable threshold. A note in the requirement says the laboratory must determine and regularly review the number of contaminated cultures. Tracking the contamination rate and providing feedback to units and persons drawing cultures is one method, it says, that has been shown to reduce contamination rates. Other measures for consideration in monitoring blood culture contamination include the types of skin disinfection used and line draws. The requirement says the threshold may be established in collaboration with other relevant institutional groups, and the laboratory must perform and record corrective action if the threshold is exceeded.

"What we're describing is best practice," Dr. Anderson explains. "It demonstrates that we are collecting this important quality assurance data, using it, and feeding it back to make sure that we are improving practices."

Dr. Campbell says these practices have always been important. "But we wanted to make it clearer to laboratories that we need to monitor and work to reduce contamination rates. This is also part of antimicrobial stewardship," he says. "Patients with contaminated blood cultures usually get put on empiric antibiotics until the nature of the contaminant is clear. We're trying to reduce the use of empiric antibiotics by asking laboratories to be more active in the preanalytic realm, to monitor and reduce blood culture contamination rates."

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