New viscoelastic testing requirement in checklist

All common, molecular, hematology and coagulation changes

Valerie Neff Newitt

September 2023—A proficiency testing accreditation requirement in the new checklist edition was revised to add clarification, and a new requirement on viscoelastic testing will close an existing gap.

They are among the changes laboratories can expect to see in the 2023 checklist edition released last month, most of which were made in response to often-asked questions or commonly cited inspection deficiencies.

Among them is COM.01600, which requires the laboratory to integrate all proficiency testing and alternative performance assessment specimen testing within the routine laboratory workload and be analyzed by personnel who routinely test patient specimens. “It’s very important that you handle proficiency testing material exactly the same way you handle patient specimens,” says Amer Mahmoud, MD, vice chair of the CAP Checklists Committee and clinical associate professor of pathology, University of New Mexico.

The CAP is often asked if a person can be assisted by another person when looking at a proficiency testing sample, and who can assist. COM.01600 now clarifies that an individual may seek assistance from other onsite personnel for morphologic examinations—identification of cell types and microorganisms—or data review (for electrophoretic patterns, for example) for PT specimens, provided patient specimens are handled in the same manner, as defined by the laboratory’s policies and procedures.

What’s critical is that the person be operating under the laboratory’s CLIA/CAP certificate, Dr. Mahmoud says. “You cannot share it with somebody out of your lab, even if you are sending patient specimens within your laboratory system to another site. The rules do not allow it.” So if a technologist seeks assistance from another technologist, the technologist who is assisting must be onsite. The only exception would be for testing specified in the Centers for Medicare and Medicaid Services memorandum QSO-23-15-CLIA, released May 11, which defines specific conditions for the remote review of PT digital images or data by pathologists or other lab personnel under the laboratory’s CLIA/CAP certificate.

Dr. Mahmoud provides an example from his own work at Presbyterian Hospital in Albuquerque and TriCore Reference Laboratories. “We do a morphologic review for blood parasite,” he says of a patient specimen. “The technologist would look at the specimen, have a preliminary result, then send it to the hematopathologist for confirmation. My office is in the hospital across the street, with a different CLIA/CAP certificate. They ship the slides to me, and I write down my notes for confirmation, send it to them, and then they release it into the record.” A proficiency testing sample, by contrast, cannot be sent to him across the street. “I go there physically to be onsite and look at it onsite. That’s because of the PT rules.”

HEM.38700 Viscoelastic Testing—Error Communication is a new requirement that says if viscoelastic testing for hemostasis analysis is performed in the laboratory and the results are viewable remotely by clinical personnel in real time, the laboratory promptly communicates analytic errors to the responsible clinical personnel.

Dr. Mahmoud

Viscoelastic testing allows for real-time visualization of clot formation and dissolution during low shear rate blood

flow. “It’s a unique type of testing because the physician who will be acting on the results has the capability to review the data in real time,” Dr. Mahmoud says, noting the instrument can be in a separate physical location from the clinician. “If there is something wrong with the instrument that will require repeating the test, doctors must be alerted promptly in real time so they don’t take action based on potentially inaccurate data.”

Under the new requirement, if the results can be reviewed remotely in real time, the laboratory has to promptly communicate the analytic errors to the responsible personnel. The laboratory must ensure staff is trained for prompt notification, and communication must be recorded. Before this requirement was added, Dr. Mahmoud says, “this was a gap in that prompt reporting wasn’t explicitly required.”

HEM.37165 Coagulation Testing and Therapeutic Anticoagulant Recommendations, which requires that recommendations be made available to clinicians for several types of tests, now also includes viscoelastic testing. The requirement, as revised, says recommendations on the utility of viscoelastic testing in clinically meaningful situations must be available, including the following as applicable: proper test selection, instrument comparability, and/or for viscoelastic testing-based monitoring of antiplatelet or anticoagulant medications.

“You need to have recommendations about the utility and limitations of viscoelastic testing in therapeutic clinical situations,” Dr. Mahmoud says. For example: “How does it compare to other methods in the laboratory that might test similar parameters?”

In the molecular pathology checklist, MOL.36155 on the classification and reporting of variants in inherited disease, oncologic, and pharmacogenomic testing requires the lab to follow defined criteria for variant classification that take into consideration professional organization recommendations and guidelines, when available.

If the laboratory elects to deviate from the guidelines, it has to explain its rationale for doing so.

What’s new in this requirement is the focus on classification, not interpretation, Dr. Mahmoud says. “We received feedback about the original wording of the requirement, which referred to variant interpretation. Variant interpretation goes to the practice of pathology—looking up the literature, making judgment calls, using your experience and methodologies,” he says. “So we changed the language to variant classification rather than interpretation.”

The language of the revised requirement is also now more flexible about the laboratory’s use of professional organization guidelines. “There is still some debate about how definitive these guidelines are. So we wanted to remain flexible and strike a reasonable balance that will encourage the labs to look into the guidelines, but not make complete adherence a must.” This is the reason for what he describes as “softened” language. “Labs have the option to deviate,” Dr. Mahmoud says, “but they should have a clear rationale for that deviation.”

In the all common checklist, there are two additional changes. One change is in the note to COM.04300, which requires the laboratory to define acceptability criteria for the comparability of nonwaived instruments and methods used to test the same analyte, and to take corrective action when criteria are not met.

The note provides examples of data that can be useful in establishing the criteria, such as method validation or verification data, clinical significance of the variation between methods, biologic variation data, and data from external PT providers.

“For example, if you are testing a certain analyte by different instruments, you should get more or less the same result regardless of what instrument was used,” Dr. Mahmoud says of the requirement. “You need to compare

instruments to make sure they give similar results. You need to establish your criteria to decide which results are considered similar and which are not.

“As you establish these criteria, you can look at your method validation or verification data,” he continues. “Each method has certain specifications in terms of accuracy and precision, and you will factor this in when determining how much variation you will allow between two instruments. As a medical director, you need to consider the clinical significance of the variation. You also can look at the biologic variation data because different analytes will vary biologically. You can look at data from external PT providers.”

New to the all common checklist but not a new requirement of laboratories is COM.30695 Biological Safety Cabinet. Previously this requirement was in the discipline-specific checklists—molecular and microbiology, to name two. Now it’s in the all common checklist and requires a certified biological safety cabinet to be available and used when appropriate.

A biological safety cabinet is used as a work practice control to protect personnel, specimens, the testing environment, or all three. The need for a BSC is determined by doing a risk assessment for the types of testing or procedures performed in the laboratory, such as handling specimens potentially containing highly transmissible infectious pathogens, the potential for aerosolization, the prevention of DNA/ RNA contamination, or maintaining sterility of cell cultures.

Moving the requirement serves two purposes, Dr. Mahmoud explains. “It standardizes the requirement across all the checklists. And if there are biologic safety cabinets in various other sections of the lab, the requirement ensures they are not missed by the inspector and are properly evaluated.”

New and revised requirements in the anatomic pathology, laboratory general, and other checklists were reported in the August issue (https://bit.ly/CT-082023).

An Oct. 18 Focus on Compliance webinar (noon to 1 PM CST, registration open at www.cap.org) will highlight key checklist changes. CAP-accredited labs can access other compliance-related resources on www.cap.org (in e-Lab Solutions Suite, log-in required, under Accreditation Resources), including past Focus on Compliance webinars and lab inspection preparation videos. Also online are answers to the most common checklist-related questions, a self- and post-inspection toolbox, and customizable templates and forms for, among other things, competency assessment and quality management.

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