New accreditation POC requirements for coagulation testing

Valerie Neff Newitt

January 2025—The point-of-care checklist in the 2024 accreditation checklist edition, released Dec. 26, now includes requirements on coagulation specimen collection and handling.

“Given the increasing presence of point-of-care assays used for coagulation testing, we felt it was time to get a handle on the rigors of what is known to be best practice for coagulation testing, whether it’s in the core lab or point of care,” says Andrew Goodwin, MD, chair of the CAP Hemostasis and Thrombosis Committee and section medical director of the thrombosis and hemostasis laboratory at the University of Vermont Medical Center.

The core lab’s own challenges with coagulation specimen and handling, he says, suggest “we need to share our experience with the colleagues who are doing point-of-care testing in coagulation.”

“We saw a potential gap and wanted to alert those doing point-of-care testing that there are a lot of variables that can impact coagulation testing,” Dr. Goodwin says, “perhaps more than many other sections of the laboratory.”

Dr. Rollins-Raval

The three new requirements in the point-of-care checklist came from the hematology and coagulation checklist. They “stem from what we’ve seen in the core laboratory,” says Marian Rollins-Raval, MD, MPH, “and we think could be an issue potentially in the point-of-care setting.” Dr. Rollins-Raval is a member of the CAP Hemostasis and Thrombosis Committee and chief of the Division of Hematopathology and Genomic Medicine at the University of Vermont Medical Center.

POC.09146 Specimen Handling for Whole Blood-Based Testing—Coagulation requires that specimens for whole-blood-based coagulation testing be handled according to the manufacturer’s instructions or as validated by the laboratory. Specimens must not be heated, refrigerated, or frozen, the requirement says, and centrifuged specimens must be rejected. Reconstitution of a centrifuged specimen by mixing is considered inadequate.

The point-of-care testing requirement is identical to HEM.36960 in the hematology and coagulation checklist. “The purpose of putting it in both checklists is to underscore its importance for both the point of care and for the in-laboratory testing of these whole blood assays,” Dr. Rollins-Raval says.

POC.09147 Specimen Handling—Platelets says blood specimens for platelet aggregation and platelet function studies must be handled at room temperature before testing. “Sometimes people wrongly think that if testing is going to be delayed a bit, why not put it on ice so that things stay stable,” Dr. Rollins-Raval says. “But all platelet function studies must be performed on a specimen that has been collected and has remained at room temperature. And platelets are very sensitive to vibrational forces as well.”

POC.09148 Coagulation Testing and Therapeutic Anticoagulant Recommendations requires that recommendations be made available to clinicians in four areas: 1) laboratory tests used for monitoring heparin, low-molecular-weight heparin, direct thrombin inhibitors such as argatroban, and/or oral anticoagulant therapy; 2) utility and limitations

of viscoelastic testing; 3) therapeutic ranges if available; and 4) potential interferences of anticoagulant medications on coagulation testing.

“In core lab areas, we provide education with the testing to make sure providers are aware of the limitations,” Dr. Rollins-Raval says. “We want to make sure that is also being done for point-of-care assays to avoid instances of users getting a value without any recommendations or reference intervals.”

The recommendation from the lab could be in an educational bulletin or in the directory of service, for example, or it could be in a comment associated with the results, she notes. “But the laboratory needs to have some sort of mechanism to be able to give this information to the clinical team.”

In Dr. Goodwin’s experience, having multiple forms of communication is likely most effective. “At our institution, our lab test catalog provides links to our educational information, we provide information in our diagnostic comments, and we try to provide at-the-elbow education when we have an opportunity, such as during a multidisciplinary patient care conference.”

The laboratory’s recommendation may differ for a particular patient population. At the University of New Mexico, where Dr. Rollins-Raval was before recently moving to the University of Vermont, the laboratory provided in its note the published reference ranges for heparin and advised clinicians to refer to local protocols or guidelines for specific populations.

Dr. Goodwin

Point-of-care devices differ too, Dr. Goodwin says. “While one point-of-care instrument might be sensitive to the presence of one anticoagulant, a different point-of-care device might not have the same sensitivity. So it’s important that laboratories work with their clinicians to help them understand which devices are able to detect or have interference from certain anticoagulants.”

For viscoelastic testing, POC.09148 requires laboratories to provide recommendations on “the utility of testing in clinically meaningful situations,” including (as applicable) proper test selection, instrument comparability, and viscoelastic-testing-based monitoring of antiplatelet or anticoagulant medications.

“Physicians need to understand there are multiple viscoelastic assays now on the market and they’re not all the same,” Dr. Goodwin says, noting their variable sensitivities to certain disease states or anticoagulants. “Guidance should be provided to physicians on what the viscoelastic assay they are using can and cannot do—its strengths and weaknesses, sensitivities and limitations.”

About coagulation testing in general at the point of care, Dr. Rollins-Raval has a final suggestion: If a new assay is being used, look at the package insert. “Sometimes there’s a disconnect between what’s in the instructions for use versus what your procedure says. Making sure they’re aligned is important. And as we’re moving into this era where there may be more FDA regulation, if you have an assay that’s FDA approved for whatever use, make sure you’re using it in the way for which it’s been approved.”

Adding these requirements for coagulation specimen collection and handling to the POC checklist, Dr. Goodwin says, is the CAP’s approach to supporting point-of-care testing, ensuring practice guidelines are followed, and ultimately helping point-of-care sites provide high-quality patient care. “We are unaware how various point-of-care sites handle whole blood specimens for coagulation testing. We’re becoming aware that the breadth of available instruments is growing quickly, and the manufacturers often go directly to the clinicians to market their products

rather than through the laboratory. Therefore, as laboratorians we want to be sure best-practice guidelines are applied at the point of care."

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