Q & A, 4/13

Editor: Frederick L. Kiechle, MD, PhD

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Submit a Question

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[pulledquote]Q. In the point-of-care test for the determination of prothrombin time and International Normalized Ratio by fingerstick in a physician's office, are controls (normal and elevated) available for adequate QC determination? Are physician office labs not governed by the same basic principles governing formal clinical laboratories? Are they permitted to run tests without running QC? Are there potential legal ramifications for having obtained an incorrect result for a POC test performed in a physician's office without the proper use of QC, leading to a catastrophic patient result?[/pulledquote]

A. Physician office laboratories (POLs) are regulated under the Clinical Laboratory Improvement Amendments of 1988, which define a laboratory as "any site where clinical laboratory testing occurs." The complexity model for test methods was introduced in CLIA '88, and three categories were established: waived, moderate complexity, and high complexity. The more complicated the test, the more stringent the requirements. Most POLs perform waived testing predominantly, if not exclusively.

Waived testing is defined under CLIA '88 as "simple laboratory examinations and procedures that are cleared by the FDA for home use, and employ methodologies that are so simple and accurate as to render the likelihood of erroneous results negligible or pose no reasonable risk of harm to the patient if the test is performed incorrectly." To perform waived tests, a laboratory must enroll in the CLIA program, pay applicable certificate fees, follow manufacturers' instructions for tests that are FDA approved for waived testing, and be inspected if complaints or issues arise.

Waived laboratory testing performed in a POL must be performed according to the manufacturer's instructions for quality control and test performance. This typically includes running controls on each new lot or shipment of test materials, and on each day of patient testing. If the manufacturer's instructions are not followed, the laboratory is not in compliance with regulations and may not only jeopardize patients but also risk losing the ability to perform POC testing. If the POL develops its own procedures for performing the test or QC that deviate from the manufacturer's instructions, regardless of how good those procedures may be, the test is then considered highly complex under CLIA '88 rules, and all the requirements for a high-complexity laboratory come into play.

Physician office laboratories may choose to be accredited by COLA, a private entity that was granted deemed status by the Centers for Medicare and Medicaid Services in 1993 and by the Joint Commission in 1997. COLA's laboratory program accredits physician offices, community hospitals, mobile clinics, and Veterans Administration and U.S. Department of Defense laboratories in the areas of chemistry, microbiology, hematology, immunology, and immunohematology/transfusion services.

Point-of-care testing for prothrombin time/International Normalized Ratio (PT/INR) is indicated for warfarin monitoring. Once the patient's dose requirements and anticoagulation effects have been stabilized for one to two weeks, using a central laboratory, testing can be moved to a point-of-care device. POC PT/INR devices have not been approved for coagulation screening or testing for disseminated intravascular coagulation, nor have they been approved for use in the trauma/emergency department setting. POC PT/INR testing is limited to the stabilized

patient for warfarin monitoring. Even when the manufacturer's instructions are followed, problems may arise that result in inaccurate test results. Offices or clinics that perform POC INR testing should be aware of the potential problems and develop policies and procedures regarding when the patient should be referred for additional testing to confirm high, low, or unstable INR results from a POC test.

References

1. Centers for Disease Control and Prevention. Clinical Laboratory Improvement Amendments, Subpart A, Section 493.5 and 493.15. wwwn.cdc.gov/clia/regs/subpart_a.aspx#493.5. Accessed Aug. 27, 2012.
2. COLA. Laboratory Accreditation. www.cola.org. Accessed Aug. 27, 2012.

Deborah A. Perry, MD
Department of Pathology
Methodist Hospital and
Children's Hospital and Medical Center
Omaha, Neb.

Chair, CAP Point-of-Care Testing Committee

Tim Hamill, MD
Department of Laboratory Medicine
University of California San Francisco

Vice Chair, CAP Point-of-Care Testing Committee

[pulledquote]Could you comment on the benefits of adding a pediatric cord blood bank capturing unit to the labor and delivery unit of a hospital in Saint Thomas, U.S. Virgin Islands?[/pulledquote]

A. The addition of a new cord blood collection facility to a maternity hospital serving an ethnically distinct population and associated with an experienced public cord blood bank will benefit the community by making available additional clinical-grade cord blood units (CBUs) for matching and transplantation. In particular, the availability of CBUs from donors of ethnic minority populations will increase the access of members of those populations to hematopoietic transplantation. The Saint Thomas, U.S. Virgin Islands, population includes (according to the 2000 census) the following ethnic groups: black 76.2 percent, white 13.1 percent, Asian 1.1 percent, mixed 3.5 percent, and other 6.1 percent, and will contribute to current national and international efforts to obtain ethnically balanced access of patients to this therapy.

The mothers and families of donors will benefit from the understanding that they have made a contribution to saving the life of another human being, a fact that will accompany the donors throughout life. The availability of this service will bring to the whole community a sense of participation in what is a truly international effort to help others.

Reference

1. Barker JN, Byam CE, Kernan NA, et al. Availability of cord blood extends allogeneic hematopoietic stem cell transplant access to racial and ethnic minorities. *Biol Blood Marrow Transplant*. 2010;16(11):1541–1548.

Pablo Rubinstein, MD

Program Director
National Cord Blood Program
New York, NY