Revised Laboratory Requirements: Immunohistochemistry and Microbiology

The Joint Commission regularly reviews program requirements alongside the latest standards of practice and professional literature to keep pace with significant developments that may necessitate modifications to requirements.

In order to capture emerging trends in laboratories and maintain alignment with the Centers for Medicare & Medicaid Services (CMS) Clinical Laboratory Improvement Amendments of 1988 (CLIA ’88) regulations, The Joint Commission recently updated two areas of the Comprehensive Accreditation Manual for Laboratory and Point-of-Care Testing (CAMLAB). Both areas are in the “Quality System Assessment for Nonwaived Testing” (QSA) chapter of the manual.

**Polymer-Based Immunohistochemistry Methods**

The first change pertains to the use of a negative control for polymer-based immunohistochemistry (IHC) methods. Polymer-based IHC methods allow for the visualization of target proteins through the use of antibodies conjugated to enzyme-labeled polymers. The polymer-based method is more sensitive than traditional techniques, and the polymers do not bind nonspecifically to the tissue sample. Because the absence of nonspecific binding eliminates the likelihood of false positive results, a negative control is not necessary for this method. This change is reflected in the revision of Standards QSA.02.10.01, EP 7 and QSA.13.06.01, EP 2 shown in the box on page 8.

**Quality Control for Microbiology Laboratories**

The second change is a result of the January 9, 2015, revision to the CMS CLIA ’88 Interpretive Guidelines that removed all references to the Clinical and Laboratory Standards Institute (CLSI) and CLSI documents. The Interpretive Guidelines previously had included exceptions for the laboratory specialty of microbiology to quality control regulations based on compliance with the CLSI documents. As a result of the revisions, however, microbiology laboratories are now required to comply with all CLIA ’88 quality control regulations. This change is reflected in the revision of Standard QSA.04.01.01, EP 2 shown in the box on page 8.

The revised requirements are currently displayed on The Joint Commission website at http://www.jointcommission.org/standards_information/prepublication_standards.aspx. In addition, they will be posted in the fall E-dition® and published in the 2016 CAMLAB.
For more information regarding these revisions, please contact Ron Quicho, associate project director, Department of Standards and Survey Methods, The Joint Commission, at rquicho@jointcommission.org or 630-792-5935.

**Revised Laboratory Requirements: Immunohistochemistry and Microbiology (continued)**

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Official Publication of Joint Commission Requirements

Revisions to Laboratory Requirements

**Applicable to Laboratories**

**Effective January 1, 2016**

**Quality System Assessment for Nonwaived Testing (QSA)**

**Standard QSA.02.10.01**

The laboratory performs quality control testing to monitor the accuracy and precision of the analytic process.

**Note:** This standard is considered in combination with the specialty and subspecialty requirements found in this chapter (for example, blood gas testing requires three levels of quality control materials each day of patient testing).

**Element of Performance for QSA.02.10.01**

C 7. The laboratory uses a negative and positive reactivity control material to check fluorescent and immunohistochemical stains for intended reactivity each day the procedure is performed. The quality control results are documented.  

**Note:** For polymer-based immunohistochemical methods, a negative control is not required.

**Standard QSA.04.01.01**

The laboratory tests chemical and biological solutions, reagents, and antisera used in bacteriology, mycobacteriology, and mycology for reactivity and deterioration.

**Element of Performance for QSA.04.01.01**

A 2. The laboratory uses a positive and, as appropriate, a negative control material for each qualitative procedure in bacteriology, mycobacteriology, and mycology, at a frequency consistent with laboratory policy or the manufacturer’s instructions, if more stringent, unless the laboratory demonstrates satisfactory performance that would qualify the laboratory to perform streamlined quality control. The quality control results are documented.

**Note 1:** Streamlined quality control is applicable only for commercial microbial identification systems (MIS) and follows the Clinical and Laboratory Standards Institute (CLSI) document, “Quality Control for Commercial Microbial Identification Systems Approved Guideline,” M50-A.

**Note 2:** A negative control is not required for the mycology germ tube test.

**Standard QSA.13.06.01**

The equipment, methods, and stains used in producing microscopic slides provide tissue sections that facilitate a diagnosis.

**Element of Performance for QSA.13.06.01**

C 2. The laboratory performs quality controls on histologic stains for intended reactivity. The quality control results are documented.

**Note:** For example, immunohistochemical (IHC) stains have positive and negative controls, and for periodic acid-Schiff (PAS) stains, documentation of typical cellular staining characteristics is acceptable. For polymer-based immunohistochemical methods, a negative control is not required.