DEPARTMENT OF HEALTH & HUMAN SERVICES Centers for Medicare & Medicaid Services 7500 Security Boulevard, Mail Stop C2-21-16 Baltimore, Maryland 21244-1850



Center for Clinical Standards and Quality/ Quality, Safety & Oversight Group

Admin Info: 23-11-CLIA

DATE: July 24, 2023

TO: State Survey Agency Directors

FROM: Director, Quality, Safety & Oversight Group (QSOG)

SUBJECT: American Society for Clinical Pathology (ASCP) Board of Certification (BOC)

Diplomate in Medical Laboratory Immunology (DMLI) Approved Board Certification for the Clinical Laboratory Improvement Amendments (CLIA)

High Complexity Laboratory Director

Memorandum Summary

- Approval of New Board Certification for High Complexity Laboratory Directors –
 The Centers for Medicare & Medicaid Services (CMS) is approving the American
 Society for Clinical Pathology (ASCP) Board of Certification (BOC) Diplomate in
 Medical Laboratory Immunology (DMLI) certification.
- Discontinuation of the American Board of Medical Laboratory Immunology (ABMLI) Certification Exam The American Society for Microbiology (ASM) ABMLI is no longer accepting exam applications; however, it will continue to recertify its Diplomates.

Background:

CMS, in collaboration with the Centers for Disease Control and Prevention (CDC), is approving the American Society for Clinical Pathology (ASCP) Board of Certification (BOC) Diplomate in Medical Laboratory Immunology (DMLI) certification as an approved board for high complexity laboratory directors. As stated in the CLIA regulations, individuals that hold an earned doctoral degree in a chemical, physical, biological, or clinical laboratory science from an accredited institution and are certified and continue to be certified by a board approved by the Department of Health and Human Services (DHHS) may qualify as a laboratory director for laboratories performing high complexity testing, as long as they possess a current license as a laboratory director issued by the State in which the laboratory is located, if such licensing is required.

Additionally, the ABMLI is no longer accepting exam applications as of June 1, 2016; however, CMS continues to recognize this certification as a means to qualify for high complexity laboratory director. Further, the ABMLI continues to recertify its Diplomates.

Discussion:

State Agencies may accept board certification from individuals that passed the ASCP BOC DMLI certification on or after April 1, 2023.

State Agencies may also continue to accept board certification from individuals that are certified and continue to be certified by ABMLI.

Contact:

For questions or concerns relating to this memorandum, please contact LabExcellence@cms.hhs.gov.

Effective Date:

Immediately. Please communicate to all appropriate staff within 30 days.

/s/
David R. Wright
Director, Quality, Safety & Oversight Group

Resources to Improve Quality of Care:

Check out CMS's new Quality in Focus interactive video series. The series of 10–15 minute videos are tailored to provider types and aim to reduce the deficiencies most commonly cited during the CMS survey process, like infection control and accident prevention. Reducing these common deficiencies increases the quality of care for people with Medicare and Medicaid. Learn to:

- *Understand surveyor evaluation criteria*
- Recognize deficiencies
- Incorporate solutions into your facility's standards of care

See the Quality, Safety, & Education Portal Training Catalog, and select Quality in Focus