DISCOVER	• If the administrator and/or the medical staff representative gave examples indicating that the laboratory did not meet their expectations, further evaluate laboratory leadership's responses, corrective actions and resolutions. • If QC failures are identified, determine whether they reflect systemic problems or involve patient safety. If so, was the laboratory director involved in the resolution? • Evaluate the laboratory director's involvement in key quality processes (proficiency testing, root cause analysis, procedure manual review, etc.) • Discuss the review of the interim self-inspection records with the Laboratory General inspector to identify issues with lack of thoroughness of the interim self-inspection or systemic problems identified during the self-inspection that have not been corrected. • Determine if there was a change of laboratory director within the last two years. If yes, confirm that the new laboratory director approved technical policies and procedures within three months of the change or that an explanation was recorded with a reasonable schedule for completion of the approval process.

QUALIFICATIONS AND GENERAL REQUIREMENTS

***REVISED** 12/26/2024*

DRA.10100 Laboratory Director Qualifications **Phase II**

The laboratory director satisfies the personnel requirements of the College of American Pathologists.

NOTE: The qualifications required by the CAP for the position of laboratory director depend on the testing performed in the laboratory. The qualifications are also dependent upon whether the laboratory is subject to US regulations.

The following table contains the laboratory director qualifications based on complexity of testing and US regulatory status:

Laboratories Subject to US Regulation	
Complexity of Testing	Qualifications
1. High complexity testing	a. MD, DO, or DPM licensed to practice in the jurisdiction where the laboratory is located (if required), **and**: i. Certification in anatomic or clinical pathology, or both, by the American Board of Pathology or American Osteopathic Board of Pathology, **or** ii. Have at least two years of experience supervising high complexity testing; **and** have at least 20 CE credit hours in laboratory practice that cover director responsibilities as defined in the DRA checklist* **OR** b. Doctoral degree (PhD or DPH) in a chemical, biological, or clinical laboratory science from an accredited institution, **and:** i. Have **current** certification by a board approved by HHS**, **and** ii. Have at least two years of laboratory training or experience or both, and

	laboratory experience directing or supervising high complexity testing **and** iii. Have at least 20 CE credit hours in laboratory practice that cover the director responsibilities defined in the DRA checklist*
2. Moderate complexity testing	a. Qualified as in (1) above **OR** b. MD, DO, or DPM, licensed to practice in the jurisdiction where the laboratory is located (if required), **and**: i. At least one year of experience supervising nonwaived laboratory testing, **and** ii. Have at least 20 CE credit hours in laboratory practice that cover director responsibilities as defined in the DRA checklist **OR** c. Doctoral degree (PhD or DPH) in a chemical, biological, or clinical laboratory science from an accredited institution, **and**: i. Have current certification by a board approved by HHS**, **and** ii. Have at least one year of experience directing or supervising nonwaived testing, **and** iii. Have at least 20 CE credit hours in laboratory practice that cover the director responsibilities defined in the DRA checklist*
3. Provider-performed microscopy (PPM)	a. MD, DO, or DPM, licensed to practice in the jurisdiction in which the laboratory is located (if required)
4. Waived tests	a. MD, DO, or DPM, licensed to practice in the jurisdiction in which the laboratory is located (if required) **OR** b. Doctoral degree (PhD or DPH) in a chemical, biological, or clinical laboratory science from an accredited institution
Laboratories not subject to US regulations	
All Complexity Levels	a. MD or DO licensed to practice in the jurisdiction where the laboratory is located (if required) **and** have **one** of the following: i. Certification in anatomic or clinical pathology; or ii. At least one year of laboratory training during medical residency/fellowship; or iii. At least two years of experience supervising high complexity testing **OR** b. Doctoral degree (PhD, DPH, or equivalent) in a chemical, biological, or clinical laboratory science **and** have **both** of the following:

	i. At least two years of clinical laboratory training or experience **and** ii. Two years of laboratory experience directing or supervising high complexity testing

**This does not apply to existing laboratory directors that have remained continuously employed in their current role since December 28, 2024.*

***A list of boards approved by CMS for doctoral scientists may be found at https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Certification_Boards_Laboratory_Directors.html*

Detailed information on qualifications for laboratory directors subject to US regulations may be found in the CAP Personnel Guidance Document located in e-LAB Solutions Suite on cap.org (log-in required) under Accreditation Resources - Accreditation Checklists.

Training and experience must relate to testing of human specimens for the purpose of diagnosing, treating, and monitoring an individual's condition.

For laboratories subject to US regulations, credentials for all personnel trained outside of the US must be reviewed to ensure that their training and qualifications are equivalent to CLIA requirements, with records of the review available on site. The equivalency evaluations should be performed by a nationally recognized organization. The following types of records may also be used to show equivalency: 1) license to practice medicine issued by the state in which the laboratory is located; or 2) laboratory personnel license in states where laboratory personnel licensure is required and qualifications are at least as stringent as CLIA. Department of Defense laboratories must evaluate equivalency using a process approved by the Center for Laboratory Medicine Services.

A single individual may direct no more than five laboratories (no including laboratory that perform only waived testing) and may not direct more laboratories than permitted by national, federal, state (or provincial), or local law.

If more stringent state or local regulations are in place for laboratory director qualifications, including requirements for licensure, they must be followed.

Additional qualifications for laboratory directors are included for the following types of testing or services:

- *For the subspecialty of **oral pathology,** the director must be certified by the American Board of Oral Pathology, American Board of Pathology, or the American Osteopathic Board of Pathology.*
- *Qualifications for **histocompatibility section directors/technical supervisors**, including continuing clinical laboratory education requirements, can be found in the Histocompatibility Checklist.*
- *For laboratories participating in the **Reproductive Laboratory Accreditation Program**, directors of laboratories performing andrology testing must meet the requirements described above for high complexity testing and have at least two years of experience in a laboratory performing andrology procedures. This experience must include quality management, quality control, inspection, accreditation, and licensing procedures, as well as andrology procedures. Requirements for embryology laboratory directors are found in the Reproductive Laboratory Medicine Checklist in RLM.10166.*
- *For laboratories participating in the **Forensic Drug Testing Accreditation Program**, specific requirements for laboratory director/scientific director are in the Forensic Drug Testing Checklist.*

Evidence of Compliance:

- ✓ Records of director qualifications appropriate to the type of laboratory and level of complexity

REFERENCES

1) Department of Health and Human Services, Centers for Medicare and Medicaid Services. Clinical laboratory improvement amendments of 1988; final rule. *Fed Register.* 2023(Dec 28):[42CFR493.1405], [42CFR493.1407] and [42CFR493.1443].
2) Department of Health and Human Services, Centers for Medicare and Medicaid Services. Clinical laboratory improvement amendments of 1988; final rule. *Fed Register.* 2004(Oct 1):1049 [42CFR493.1357]
3) Department of Health and Human Services, Centers for Medicare and Medicaid Services. Clinical laboratory improvement amendments of 1988; final rule. *Fed Register.* 2004(Oct 1):979 [42CFR493.19]
4) College of American Pathologists. *CAP Laboratory Accreditation Program Standards for Accreditation.* Northfield, IL: CAP; 2023.
5) Department of Health and Human Services, Centers for Medicare and Medicaid Services. Clinical laboratory improvement amendments of 1988; final rule. *Fed Register.* 2004(Oct 1): [42CFR493.1445(d)].

DRA.10125 Director Qualifications - Biorepositories Only — Phase II

The qualifications of director of the biorepository are appropriate for the scope of activities.

NOTE: The director must have had four or more years of full-time general laboratory training and experience of which at least two years were spent acquiring proficiency in biorepository operations and management. The director must be qualified to assume professional, scientific, organizational, administrative, and educational responsibilities for the services provided. The director's experience and qualifications must also meet the institutional policy for the degree of responsibility acceptable to operate and manage the scope of the biorepository.

*****REVISED** 12/26/2024***

DRA.10150 Provision of Anatomic Pathology (AP) Services — Phase II

Anatomic pathology services are provided by a pathologist certified in anatomic pathology. Exceptions for other qualified individuals for specific subspecialties are described in the NOTE.

NOTE: In facilities where anatomic pathology services are provided, a pathologist certified in anatomic pathology must perform such services. Pathologists who qualified to provide these services prior to December 28, 2024, may continue to provide these services if they have done so continuously in a CLIA-certified laboratory. The services of a consulting anatomic pathologist shall be retained if necessary.

The following are exceptions for specific types of tissue diagnosis for non-pathologist individuals:

- *Neuromuscular pathology specimens may be interpreted by an MD or DO who is licensed to practice in the jurisdiction where the laboratory is located (if required) and has completed a training program in neuromuscular pathology approved by HHS (ie, the American Academy of Neurology Committee for Neuromuscular Pathology Training Program).*
- *Other exceptions for dermatopathology, ophthalmic pathology and oral pathology as defined in the CLIA regulation 42CFR493.1449(f) and (g).*

***For laboratories not subject to US regulations**, individuals must meet national, state or provincial, or local laws and regulations, and education must be equivalent to US qualifications.*

Evidence of Compliance:

- ✓ Listing of AP services provided by the institution **AND**
- ✓ Records of pathologist qualifications (eg, degree, license, board certification, training and experience)

REFERENCES

1) Department of Health and Human Services, Centers for Medicare and Medicaid Services. Clinical laboratory improvement amendments of 1988; final rule. *Fed Register.* 2023(Dec 28):[42CFR493.1449(f)(g)].

DRA.10200 Section Director/Technical Supervisor Qualifications — Phase II