

Inspector Instructions:



- Records of personnel qualifications

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

CYG.50000 Section Director/Technical Supervisor Qualifications - Cytogenetics

Phase II

The cytogenetics laboratory has a qualified physician or doctoral scientist as section director/technical supervisor.

NOTE: The section director/technical supervisor of the cytogenetics laboratory must 1) be a doctor of medicine, doctor of osteopathy licensed to practice medicine in the state in which the laboratory is located; or 2) hold an earned doctoral degree in a biological science or clinical laboratory science from an accredited institution, or 3) meet the educational requirement found in CLIA regulation 42CFR493.1443(b)(3)(i)(B). More detailed information on the educational requirements can 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.

In addition, the section director must have either a) successfully completed an accredited fellowship with an emphasis on clinical cytogenetics and have at least four years of training or experience, or both (including the fellowship), in genetics, two of which in clinical cytogenetics; or b) in the absence of fellowship training, have four years of training or experience, or both, in human medical genetics or pathology, two of which are in clinical cytogenetics.

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

For laboratories not subject to US regulations, the section director may be either a doctor of medicine or have a doctoral degree in an appropriate science. In either case, the individual must have four or more years of fulltime general laboratory training and experience, of which at least two years were in clinical cytogenetics.

Evidence of Compliance:

- ✓ Records of section director/technical supervisor qualifications including diploma, transcript(s), primary source verification report, equivalency evaluation, board certification, or current license (if required) **AND**
- ✓ Records of work history in related field

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(i)].

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

CYG.50180 General Supervisor Qualifications - Cytogenetics

Phase II

The cytogenetics general supervisor has at least a bachelor's degree in a chemical, biological, clinical or medical laboratory science, or medical technology with at least two years of experience in clinical cytogenetics under a qualified director (as defined in CYG.50000).

Evidence of Compliance:

- ✓ Records of qualifications including diploma, transcript(s), primary source verification report, equivalency evaluation, board certification, or current license (if required) **AND**
- ✓ Records of work history in related field