



STATE OF CONNECTICUT

DEPARTMENT OF PUBLIC HEALTH

FACILITY LICENSING & INVESTIGATIONS SECTION

Request for Change in Director of a Licensed Clinical Laboratory

Per the Connecticut General Statutes § 19a-30 (d) _____,
(Name of the Licensee)

the licensee granted Connecticut Clinical Laboratory License No. _____, hereby informs the
(License No.)

Department of Public Health of a change in the administration of the laboratory.

_____ is/has succeeded
(Name of New Director)

_____ as the
(Name of Former Director)

Laboratory Director for the entity that holds the aforementioned license. This change will be/was made effective on _____, _____ 20_____.
(Month) (Day) (Year)

Qualifications of the New Director

For **High Complexity** Testing, the proposed new director (check only the ones apply):

- Is a licensed physician, certified in Anatomic and/or Clinical Pathology by the American Board of Pathology or the American Osteopathic Board of Pathology.
- Connecticut Physician License Number:
- Copy of Anatomic and/or Clinical Pathology Certification from ABP/AOBP included with this submission? (required)
- Is a licensed physician with two (2) years of directing/ supervisory experience in high complexity testing and 20 CME credits.
- Connecticut Physician License Number:

Copies of certifications, training records, CMS-209 forms demonstrating proposed director served as testing personnel in a supervisory capacity attached? (required)

- Documentation of 20 CME credits attached (required)
- Holds a Ph.D. and is board certified (CMS approved) by:
- Two (2) years of directing/supervising experience in high complexity testing + 2years of laboratory testing experience; and 20 CME credits.
- Copy of doctoral degree attached (required)

- Copy of current board certification attached? *(required)*
- Documentation of 20 CME credits attached (required)
- Previously qualified as the director of a high complexity laboratory CLIA on or before December 28, 2024, and done so continuously since then. Number of laboratories where individuals served as directors *(required)*.

For **Moderate Complexity** Testing, the proposed new director qualifies as above, or has earned a (check only the ones apply):

- Is a licensed physician, certified in Anatomic and/or Clinical Pathology by the American Board of Pathology or the American Osteopathic Board of Pathology.
- Connecticut Physician License Number:
- Copy of Anatomic and/or Clinical Pathology Certification from ABP/AOBP included with this submission? *(required)*
- Is a licensed physician with one (1) year of directing/ supervisory experience in moderate complexity testing and 20 CME credits.
- Connecticut Physician License Number:

Copies of certifications, training records, CMS-209 forms demonstrating proposed director served as testing personnel in a supervisory capacity attached? *(required)*

- Documentation of 20 CME credits attached *(required)*
- Doctoral degree in medicine, dentistry, or in a chemical, physical, biological, or clinical laboratory science and has at least one (1) year of experience directing/supervising nonwaived testing and 20 CME credits.
- Holds a Ph.D. and is board certified (CMS approved) by:
- One (1) year of directing/supervising experience in moderate complexity testing; and 20 CME credits.
- Copy of doctoral degree attached *(required)*
- Copy of current board certification attached? *(required)*
- Documentation of 20 CME credits attached *(required)*
- Master's degree in chemical, physical, biological, or clinical laboratory science and has at least one (1) year of experience directing/supervising; and one (1) year laboratory training/experience in non-waived testing; and 20 CME credits.
- Copy of master's degree included *(required)*
- Documentation of 20 CME credits attached *(required)*

Evidence of experience included *(may include certifications, CMS-209 forms, training records, CVs and resumes are **not** acceptable)*.

- Bachelor's degree in chemical physical or biological science, or medical technology and at least two (2) years of laboratory training/experience in non-waived testing; **and** at least two (2) years of supervisory laboratory experience in non-waived testing; and 20 CME credits.
- Copy of bachelor's degree included *(required)*
- Documentation of 20 CME credits attached *(required)*

Evidence of experience included *(may include certifications, CMS-209 forms, training records, CVs and resumes are **not** acceptable)*.

- Previously qualified as the director of a high complexity laboratory CLIA on or before December 28, 2024, and done so continuously since then. Number of laboratories where the individual served as director *(required)*.

Attestation

I, the undersigned, certify that the owner of the above-mentioned laboratory has employed me to fill the position of Laboratory Director, and that I in good faith submit to the Department that I am qualified to direct the laboratory testing of the laboratory per the Regulations of Connecticut State Agencies §19a-36-D33. I understand that I must also qualify to fill this position in accordance with the provisions of the Clinical Laboratory Improvement Amendments of 1988 (CLIA) and that documentation of my qualifications to serve as Laboratory Director are included with this request. I understand that the licensee and myself are jointly and severally responsible for the operation of the laboratory in compliance with R.C.S.A § 19a-36D20 through 19a-36-D38, including, but not limited to, the work of subordinates, the proper management of patient specimens and records, proper performance of all tests, and continual application of quality control procedures to this work in accordance with recommendations and directives of the Department. Furthermore, I attest that the information provided within this request is true and accurate and that I understand making a false written statement that I do not believe to be true to a public servant in the performance of such public servant's official function(s) is a Class A Misdemeanor in the State of Connecticut per C.G.S. § 53a-157(b).

(Printed Name of New Director)

(Printed Name of Owner/Responsible Officer of the Licensee)

(Signature of the New Director)

(Signature of the Owner/Responsible Officer of the Licensee)

Note that all director changes are subject to the approval of the Department of Public Health. All director change forms for licensed laboratories that also hold a CLIA Certificate of Compliance must include a completed CMS-116 form and a completed CMS-209 form with submission of this document.