

SECTION 4: Lab Director Attestation

The Laboratory Director must read, complete, and sign a Director's Attestation form.

Effective

I attest that effective, / / , I am the laboratory director, of:
Date: M M D D Y Y

Name of Laboratory: _____

Clinical laboratory located at: _____

CLIA ID: State ID:

Statements

As the director, I assume all directorship responsibilities for the Commonwealth of Pennsylvania purposes. I understand that as a director of this laboratory, I am responsible for the accuracy and reliability of all testing performed and for ensuring that the laboratory meets and will continue to meet the requirements of the Clinical Laboratory Act (CLA), 35 P.S. § 2151 - § 2165, and its regulations, 28 Pa. Code § 5.1 - § 5.104.

I understand that as the director of a laboratory performing only waived testing, I am required to be continuously available virtually to the laboratory during all times when testing is performed, to provide telephone or electronic consultation as needed. I understand that as a director of a laboratory performing non-waived testing, I must be onsite once every 6 months, with at least 4 months between the minimum two on-site visits. I understand that I may elect to be on-site more frequently. I understand that the laboratory director's responsibility to conduct on-site visits may not be delegated. I understand that I am required to provide documentation of the on-site visits, including evidence of performing activities that are part of the laboratory director's responsibilities, upon request by the Department of Health.

I understand that the Department reserves the right to perform an on-site inspection of any laboratory under my direction and may examine all matters related to clinical laboratory testing. I understand that any false statement or representation of material fact in obtaining or retaining the State licensure may be grounds for revocation of the laboratory's State permit. (Pa code § 5.93(3)).

I understand that I will be held jointly and severally responsible with the laboratory owner(s) for the operation of clinical laboratory in compliance with pertinent regulatory and statutory requirements. (28 Pa Code § 5.22 (d)). The Department will deny an application for a State permit and suspend or revoke a current permit for the laboratory's failure to maintain proper standards of accuracy, for unethical practices, unethical advertising, or for any other cause deemed adequate by the department. (28 Pa. Code § 5.91). The Department will revoke a permit for other violations of applicable regulatory and statutory requirements. (28 Pa. Code § 5.93(7)).

I understand that I will be responsible, along with the laboratory owners(s), to notify the Department in writing of any changes in the laboratory ownership, directorship, name or location within 30 days of the change. (28 Pa. Code § 5.22). The State permit shall become void for failure to provide notification of a change of director and laboratory location. (28 Pa. Code § 5.92).

I understand that I will continue to be held responsible as a laboratory director of this laboratory until the Department receives a signed Change of Status form from the laboratory notifying the Department of a change of director with the credentials of the new laboratory director.

I affirm under penalty of perjury, that all information I have given in this document is true.

Director Printed Name

Director Signature

Date: / /
M M D D Y Y

Director's Address: _____

Direct Contact Number: () -