

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 08D0706140	(X3) Date Survey Completed 09/23/2025
Name of Provider or Supplier Nemours Children's Hospital-Delaware	Street Address, City, State 1701 Rockland Road Rc1 Lab 155, Wilmington, DE	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D0000	A Recertification Survey was initiated on September 23, 2025 at approximately 9:30 AM. The laboratory was surveyed according to 42 CFR Part 493 Clinical Laboratory Improvement Amendments (CLIA) requirements. Deficiencies were identified as follows:
D6076	<p>LABORATORY DIRECTOR CFR(s): 493.1441</p> <p>The laboratory must have a director who meets the qualification requirements of 493.1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart.</p> <p>This CONDITION is not met as evidenced by: Based on interview and facility document review, the laboratory failed to ensure that 1 of 1 individual reviewed met the regulatory requirements to serve as the Laboratory Director (LD) for high complexity testing. Findings included: The laboratory failed to ensure LD/Clinical Consultant (CC) #1 was licensed to practice in the state of Delaware (Refer to D6078).</p>
D6078	<p>LABORATORY DIRECTOR QUALIFICATIONS CFR(s): 493.1443</p> <p>The laboratory director must be qualified to manage and direct the laboratory personnel and performance of high complexity tests and must be eligible to be an operator of a laboratory within the requirements of subpart R. (a) The laboratory director must possess a current license as a laboratory director issued by the State in which the laboratory is located, if such licensing is required; and (b) The laboratory director must-- (b)(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (b)(1)(ii) Be certified in anatomic or clinical pathology, or both, by the American Board</p>

of Pathology or the American Osteopathic Board of Pathology; or (b)(2)(i) Be a doctor of medicine, a doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and (b)(2)(ii) Have at least 2 years of experience directing or supervising high complexity testing; and (b)(2)(iii) Have at least 20 CE credit hours in laboratory practice that cover the director responsibilities defined in 493.1445; or (b)(3)(i)(A) Hold an earned doctoral degree in a chemical, biological, clinical or medical laboratory science or medical technology from an accredited institution; or (b)(3)(i)(B) Hold an earned doctoral degree; and (b)(3)(i)(B)(1) Have at least 16 semester hours of doctoral level coursework in biology, chemistry, medical technology (MT), clinical laboratory science (CLS), or medical laboratory science (MLS); or (b)(3)(i)(B)(2) An approved thesis or research project in biology/chemistry/MT/CLS/MLS related to laboratory testing for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings; and (b)(3)(ii) Be certified and continue to be certified by a board approved by HHS; and (b)(3)(iii) Have at least 2 years of: (b)(3)(iii)(A) Laboratory training or experience, or both; and (b)(3)(iii)(B) Laboratory experience directing or supervising high complexity testing; and (b)(3)(iv) Have at least 20 CE credit hours in laboratory practice that cover the director responsibilities defined in 493.1445; or (b)(4) Notwithstanding any other provision of this section, an individual is considered qualified as a laboratory director of high complexity testing under this section if they were qualified and serving as a laboratory director of high complexity testing in a CLIA-certified laboratory as of December 28, 2024, and have done so continuously since December 28, 2024. (b)(5) For the subspecialty of oral pathology, be certified by the American Board of Oral Pathology, American Board of Pathology, or the American Osteopathic Board of Pathology.

This STANDARD is not met as evidenced by:

Based on interview and facility document review, the laboratory failed to ensure that 1 of 1 individual reviewed met the regulatory requirements to serve as the Laboratory Director (LD) for high complexity testing. Specifically, the laboratory failed to ensure LD/Clinical Consultant (CC) #1 was licensed to practice in the state of Delaware. Findings included: A facility document titled, "Laboratory Director Responsibilities, Duties and Delegation," signed by LD/CC #1 on 09/03/2025, revealed no information regarding the qualifications or requirements required to serve as the LD. The laboratory's "Clinical Laboratory Improvement Amendments (CLIA) Application for Certification" (Form CMS-116), signed by LD/CC #1 on 8/19/2025, revealed LD/CC #1 documented a laboratory director change that was effective as of 09/01/2025. The laboratory's "Laboratory Personnel Report (CLIA)" form (Form CMS-209), signed by LD/CC #1 on 09/18/2025, revealed LD/CC #1 was listed as the laboratory's current LD and CC. LD/CC #1's "Curriculum Vitae and Bibliography" revealed LD/CC #1 was licensed as a medical doctor (MD) in the state of Florida. There was no documented evidence that LD/CC #1 was licensed to practice in the state of Delaware. During an interview on 09/23/2025 at 11:00 AM, Technical Supervisor (TS)/General Supervisor (GS) #5 stated she was aware of the requirement for the LD to be licensed in the state in which the laboratory was located. TS/GS #5 stated that the laboratory's previous LD announced in 06/2025 that they were retiring as of 09/01/2025. According to TS/GS #5, LD/CC #1 was identified as the new LD. TS/GS #5 stated LD /CC #1 submitted an application to practice in the state of Delaware, but the application was still pending approval.