

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  33D2187353	<b>(X3) Date Survey Completed</b>  05/29/2024
<b>Name of Provider or Supplier</b>  Applied Dna Clinical Labs, Llc	<b>Street Address, City, State</b>  25 Health Sciences Drive, Rm120, Stony Brook, NY	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D0000</b>	<p>A federal surveyor from the Centers for Medicare &amp; Medicaid Services (CMS) Survey Branch conducted an announced CLIA validation survey at Applied DNA Clinical Labs, LLC on May 29, 2024. The laboratory was surveyed under 42 CFR part 493 CLIA regulations. The laboratory was found to not be in compliance with all condition-level CLIA requirements. The following condition and standard-level deficiencies were found during CLIA exempt-state validation survey performed on May 29, 2024.</p>
<b>D6076</b>	<p><b>LABORATORY DIRECTOR</b> 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 review of the Laboratory Director (LD) educational credentials and interview with the LD, the Chief Operating Officer (COO), and the CEO, the LD failed to meet the qualification requirements of 493.1443 from June 13, 2023 to May 30, 2024. Findings Include: 1. Refer to D6078.</p>
<b>D6078</b>	<p><b>LABORATORY DIRECTOR QUALIFICATIONS</b> 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</p>

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 of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (b)(2) 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)(i) Have at least one year of laboratory training during medical residency (for example, physicians certified either in hematology or hematology and medical oncology by the American Board of Internal Medicine); or (b)(2)(ii) Have at least 2 years of experience directing or supervising high complexity testing; or (b)(3) Hold an earned doctoral degree in a chemical, physical, biological or clinical laboratory science from an accredited institution and-- (b)(3)(i) Be certified and continue to be certified by a board approved by HHS; or (b)(3)(ii) Before February 24, 2003, must have served or be serving as director of a laboratory performing high complexity testing and must have at least-- (b)(3)(ii)(A) Two years of laboratory training or experience, or both; and (b)(3)(ii)(B) Two years of laboratory experience directing or supervising high complexity testing. (b)(4) Be serving as a laboratory director and must have previously qualified or could have qualified as a laboratory director under regulations at 42 CFR 493.1415, published March 14, 1990 at 55 FR 9538, on or before February 28, 1992; or (b)(5) On or before February 28, 1992, be qualified under State law to direct a laboratory in the State in which the laboratory is located; or (b)(6) For the subspecialty of oral pathology, be certified by the American Board of Oral Pathology, American Board of Pathology, the American Osteopathic Board of Pathology, or possess qualifications that are equivalent to those required for certification.

This STANDARD is not met as evidenced by:

Based on review of the Laboratory Director (LD) educational credentials and interview with the LD, the Chief Operating Officer (COO), and the CEO, the LD failed to meet the qualification requirements of 493.1443 from June 13, 2023 to May 30, 2024. Findings Include: 1. Review of the LD's educational qualifications on May 29, 2024 at 2:00 pm revealed, the LD completed a doctor in medicine in the China equivalent to a doctors of Medicine degree from the united states, a New York State Department of Health certificate of qualification, and a registration certificate for a clinical laboratory technologist. 2. On May 29, 2024, the laboratory could not provide a state licensed physician registration certificate for the current LD. 3. Per the CMS 116 signed by the LD on May 7, 2024 the laboratory Virology annual test volume is 146,473. 4. Interview with the LD, COO and CEO on May 29, 2024 at 3:45 pm, confirmed the findings above.