

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D2124965	(X3) Date Survey Completed 03/05/2020
Name of Provider or Supplier Ace Biomedical Labs Llc	Street Address, City, State 6444 Beach Blvd, Jacksonville, FL	
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 complaint investigation was conducted on 3/5/20 at Ace Biomedical Labs Llc, a clinical laboratory in Jacksonville, Florida. Ace Biomedical Labs Llc was not in compliance with Code of Federal Regulations (CFR) 42, Part 493, Laboratory Requirements.
D6063	<p>LABORATORY TESTING PERSONNEL CFR(s): 493.1421</p> <p>The laboratory must have a sufficient number of individuals who meet the qualification requirements of 493.1423, to perform the functions specified in 493.1425 for the volume and complexity of tests performed.</p> <p>This CONDITION is not met as evidenced by: Based on observation and interview, it was determined that the staff member who performed pre-analytic and analytic portions of testing in an Independent Laboratory does not possess a current license issued by the state of Florida to be compliance by state law. (Refer to D6064)</p>
D6064	<p>TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(a)</p> <p>Each individual performing moderate complexity testing must possess a current license issued by the State in which the laboratory is located, if such licensing is required.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview, it was determined that Testing Person 1 does not possess a current license issued by the state of Florida to be compliance by state law. Findings include: During the review of lab personnel records, it was revealed that Testing Person 1 is not licensed in State of Florida as a clinical laboratory technologist</p>

or clinical laboratory technician. During an interview with the laboratory owner on 3/5/20 at approximately 11:22 AM, he confirmed that the Testing Person 1 is not licensed in State of Florida as clinical laboratory technologist or clinical laboratory technician, and had assisted the Technical Supervisor with loading the instruments and performing maintenance. CHAPTER 64B3-10 SCOPE OF PRACTICE FOR CLINICAL LABORATORY PERSONNEL of the Florida Administrative Code states "(1) The scope of practice for licensed clinical laboratory personnel includes specimen collecting, processing, storing, shipping and performing manual pretesting procedures. (2) The scope of practice for licensed clinical laboratory technologists, supervisors and directors includes interpretation of clinical laboratory test results." The Florida Statute Chapter 483, Part II: Clinical Laboratory Personnel states "The protection of public and individual health requires the licensure of clinical laboratory personnel who meet minimum requirements for safe practice. 483.813 Clinical laboratory personnel license.-A person may not conduct a clinical laboratory examination or report the results of such examination unless such person is licensed under this part to perform such procedures."