

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  10D0284781	<b>(X3) Date Survey Completed</b>  12/03/2021
<b>Name of Provider or Supplier</b>  Immuno Laboratories Inc	<b>Street Address, City, State</b>  6801 Powerline Rd, Fort Lauderdale, FL	
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>	A recertification survey conducted on 12/02/2021-12/03/2021, found the Immuno Laboratories Inc clinical laboratory was not in compliance with 42 CFR Part 493, Requirements for Laboratories.
<b>D3031</b>	<p><b>RETENTION REQUIREMENTS</b> CFR(s): 493.1105(a)(3)</p> <p>Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to locate and retain Specific IgG Immuno Bloodprint Applied Microarray quality control (QC) records that established control lot values for C1, C2, C3 and C4 for the year of 2020. Findings included: Review of Specific IgG Immuno Bloodprint Applied Microarray 2020 QC lot records revealed mean control lot value records were not present for C1 , C2, C3 and C4 for the year of 2020. During an interview on 12/03/2021 at 11:00 AM, the technologist stated that the previous laboratory supervisor would establish Specific IgG Immuno Bloodprint Applied Microarray QC lot values and did not retained the documents. During an interview on 12/03/2021 at 12:30 PM, the laboratory supervisor confirmed that Specific IgG Immuno Bloodprint Applied Microarray control lot values for C1, C2, C3 and C4 were missing for 2020.</p>
<b>D5217</b>	<p><b>EVALUATION OF PROFICIENCY TESTING PERFORMANCE</b> CFR(s): 493.1236(c)(1)</p> <p>At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.</p>

This STANDARD is not met as evidenced by:  
Based on lack of records and General Supervisor (GS) interview, the laboratory failed to verify the accuracy of testing methods at least twice annually for Candida Specific Immunoglobulin G (IgG) and for Candida Antibody Immunodiffusion tests for 2 out of 2 years reviewed (2020-2021). Findings included: -Review of testing records revealed that the laboratory performed the tests: Phadia ImmunoCAP 250 Candida Specific IgG and Candida antibody immunodiffusion in the years 2020 and 2021. - Review of College of American Pathologists (CAP) proficiency testing (PT) and split sample study records showed that the tests of reference were not included. -The laboratory performed 448 tests for each method during the period of reference. During an interview on 12/03/2021 at 12:00 pm with GS, she confirmed that the laboratory failed to verify accuracy at least twice a year for the methods of reference.