

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  10D0284781	<b>(X3) Date Survey Completed</b>  11/05/2025
<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>	An announced CLIA recertification survey was conducted at IMMUNO LABORATORIES INC on October 23, 2025 to November 5, 2025 The laboratory was surveyed under 42 CFR Part 493 CLIA requirements. Standard deficiencies cited are as follows:
<b>D5209</b>	<p><b>PERSONNEL COMPETENCY ASSESSMENT POLICIES</b> CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p> <p>This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory procedure manual failed to include how to do competency evaluation for Supervisors since 04/03/2025. Findings included: 1-Review of FORM CMS 209 signed by the Laboratory Director on 10/23 /2025, revealed the following: Laboratory Director (LD) was also Clinical Consultant, the Technical Supervisor (TS) for Diagnostic Immunology, General Supervisor (GS) and Testing Personnel (TP) #1 was the same person, the laboratory listed TP#2 as current TP and TP#3, TP#4, TP#5 and TP#6 were former employees. 2-Review of personnel records revealed that annual competency for TS and GS as Supervisor was evaluated on 06/13/2025 by TP#3, who had no delegation to do competence to a Supervisor. 3-Review of Policy Annual Review laboratory competency training signed by the Laboratory Director on 04/03/2025, revealed that the policy failed to include how will evaluate Supervisors and the designee for that competency evaluation. 4-During an interview on 10/23/2025 at 10:13 AM, the TS confirmed that TP#3 did the evaluation of the competency as Supervisor and that the procedure manual did not include who will do competency for a Supervisor.</p>
<b>D5805</b>	TEST REPORT

CFR(s): 493.1291(c)

(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.

This STANDARD is not met as evidenced by:

Based on review of Patient reports and staff interview, the laboratory failed to include the name of the laboratory that performed the Immunology specialty testing on 2 out of 4 (Patients #1, #2, #3, and #4) reports reviewed. Findings included: 1- Review of random patient final reports pulled 03/21/2024 (#1), 09/03/2024 (#2), 04/03/2025 (#3), and 10/21/2025 (#4), revealed that two reports (#2 and #4) did not have the laboratory location where the testing was performed. 2- During interview on 10/23/2025 at approximately 1:25 PM, the General Supervisor confirmed that the Laboratory's physical location was not on the final reports.

**D6121**

**TECHNICAL SUPERVISOR RESPONSIBILITIES**

CFR(s): 493.1451(b)(8)(i)

The procedures for evaluation of the competency of the staff must include, but are not limited to-- (b)(8)(i) Direct observations of routine patient test performance, including patient preparation, if applicable, specimen handling, processing and testing;

This STANDARD is not met as evidenced by:

Based on record review and staff interview, the Technical Supervisor (TS) or a designee failed to do direct observation of patient testing during competency evaluation for testing personnel (TP)# 1 in 2025. Findings included: 1-Review of FORM CMS 209 signed by the Laboratory Director on 10/23/2025, revealed the following: Laboratory Director (LD) was also Clinical Consultant, the Technical Supervisor (TS) for Diagnostic Immunology, General Supervisor (GS) and Testing Personnel (TP) #1 was the same person, the laboratory listed TP#2 as current TP and TP#3, TP#4, TP#5 and TP#6 were former employees. 2-Review of personnel records revealed that annual competency for TP#1 for the Microarray slide preparations, revealed that the annual competency for patient testing was observed by TP#3 on 01/06/2025. TP#3 had no delegation letter to do competency. 3-During an interview on 10/23/2025 at 12:14 AM, the TS confirmed that the TP#3 had no delegation for observation of patient testing during annual competency for TP#1 on 01/06/2025.

**D6124**

**TECHNICAL SUPERVISOR RESPONSIBILITIES**

CFR(s): 493.1451(b)(8)(iv)

(b)(8)(iv) Direct observation of performance of instrument maintenance and function checks;

This STANDARD is not met as evidenced by:

Based on record review and staff interview, the Technical Supervisor (TS) or a designee failed to do direct observation of performance of instrument and function check during competency evaluation for testing personnel (TP)# 1 in 2025. Findings included: 1-Review of FORM CMS 209 signed by the Laboratory Director on 10/23/2025, revealed the following: Laboratory Director (LD) was also Clinical Consultant, the Technical Supervisor (TS) for Diagnostic Immunology, General Supervisor (GS) and Testing Personnel (TP) #1 was the same person, the laboratory listed TP#2 as another current TP and TP#3, TP#4, TP#5 and TP#6 were former employees. 2-Review of personnel records revealed that annual competency for TP#1 for the Microarray slide preparations, revealed that the annual competency performance of instrument and function check was observed by TP#3 on 01/06/2025. TP#3 had no delegation letter to do competency. 3-During an interview on 10/23/2025 at 12:14 AM, the TS confirmed that the TP#3 had no delegation for observation of performance of instrument and function check during annual competency for TP#1 on 01/06/2025.