

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 21D0957235	(X3) Date Survey Completed 06/15/2026
Name of Provider or Supplier Immunopathogenesis Section	Street Address, City, State 10 Center Drive, Bethesda, MD	
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	An onsite Recertification survey was conducted on June 15, 2026. The following standard-level deficiencies were cited.
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES 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 a review of the quality assurance plan (QAP), lack of a supervisory competency assessment procedure, and an interview with the technical supervisor (TS) and testing personnel (TP), the laboratory failed to have a policy or procedure in place to assess the competency of 1 of 1 TS/ general supervisor (GS) for their delegated responsibilities. Findings: 1. Review of laboratory policies and procedures on June 15, 2026, revealed that the QAP section assessment outlined competency assessment for testing personnel. The policy failed to address competency assessment for the TS/GS responsibilities." 2. The laboratory failed to provide a policy or procedure for the assessment of competency for the TS/GS listed on form CMS 209. 3. By interview on June 15, 2026, at 1:30 pm, the TS confirmed they were not assessed for their delegated responsibilities as a TS and GS.</p>
D5217	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE 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 review of the quality assurance plan (QAP), lack of proficient testing records, and interview with the technical supervisor (TS) and testing personnel (TP), the laboratory failed verify the accuracy for Anticytokine autoantibody screen testing performed on the Bioplex at least twice annually for 2 of 2 years (2024 and 2025). Findings: 1. The QAP under proficiency testing and competency checks stated, "At least annually, a previous tested specimen is repeated that comparable results are obtained". 2. Review of the records on June 15, 2026 revealed, the laboratory failed to perform proficiency testing or verify the accuracy for Anticytokine autoantibody screen testing performed at least twice annually in 2 years (2024 and 2025) on the Bioplex. 3. In an interview on June 15, 2026, at 2:20 pm the TS and TP confirmed proficiency testing or verification of accuracy for Anticytokine autoantibody screen testing was only performed annually during the TP's annual competency assessment.

D5293

GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT
CFR(s): 493.1239(b)(c)

(b) The general laboratory systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of general laboratory systems quality assessment reviews with appropriate staff. (c) The laboratory must document all general laboratory systems quality assessment activities.

This STANDARD is not met as evidenced by:
Based on review of Quality Assurance Plan, lack of documented quality assurance (QA) activities and interview with technical supervisor (TS) and testing personnel (TP), the laboratory failed to assess and document general laboratory system activities performed for 2 of 2 years (June 2024 to June 2026). Findings: 1. The Quality Assurance Plan stated, "The QA program is designated to: - Evaluate the effectiveness of the laboratory policies and procedure - Identify and correct problem - Ensure accurate, reliable and prompt reporting of test results - Ensure the adequacy and competency of the laboratory staff - Meet all regulatory requirements and they apply to the services offered" 2. The above plan did not address ongoing QA activities for the laboratory's general systems and overall system effectiveness as required by 493.1231 through 493.1236. 3. The laboratory failed to provide documentation for all general laboratory systems QA activities performed for 2 years (June 2024 to June 2026). 4. In an interview on June 15, 2026 at 2:00 pm, the TS and TP confirmed the above findings.

D5393

PREANALYTIC SYSTEMS QUALITY ASSESSMENT
CFR(s): 493.1249(b)(c)

(b) The preanalytic systems assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of preanalytic systems quality assessment reviews with appropriate staff. (c) The laboratory must document all preanalytic systems quality assessment activities.

This STANDARD is not met as evidenced by:
Based on review of Quality Assurance Plan, lack of documented quality assurance (QA) activities and interview with technical supervisor (TS) and testing personnel

(TP), the laboratory failed to assess and document preanalytic system activities performed for 2 of 2 years (June 2024 to June 2026). Findings: 1. The Quality Assurance Plan stated, "The QA program is designated to: - Evaluate the effectiveness of the laboratory policies and procedure - Identify and correct problem - Ensure accurate, reliable and prompt reporting of test results - Ensure the adequacy and competency of the laboratory staff - Meet all regulatory requirements and they apply to the services offered" 2. The above plan did not address ongoing QA activities for preanalytic systems effectiveness as required by 493.1241 through 493.1242. 3. The laboratory failed to provide documentation for preanalytic system activities performed for 2 years (June 2024 to June 2026). 4. In an interview on June 15, 2026 at 2:00 pm, the TS and TP confirmed the above findings.

D5413

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT
CFR(s): 493.1252(b)

(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (b)(1) Water quality. (b)(2) Temperature. (b)(3) Humidity. (b)(4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.

This STANDARD is not met as evidenced by:

Based on review of quality assurance plan, review of manufactures instructions and interview with the technical supervisor (TS) and testing personnel (TP), the laboratory failed to define humidity requirements for the Bio Plex 200 system in use to perform Anticytokine Autoantibody screen testing for 2 of 2 years. Findings: 1. Review of the quality assurance plan under equipment monitoring revealed, the laboratory did not establish references ranges to monitor the laboratories humidity. 2. The Biorad Bioplex 200 system hardware instruction manual, Section 6 Bio Plex 200 system specifications, Environmental conditions stated (page 36), "operating humidity 20-80%, non-condensing". 3. By interview on June 15, 2026 at 2:12 pm, the TS and TP confirmed the laboratory did not establish a reference ranges for humidity.

D5431

MAINTENANCE AND FUNCTION CHECKS
CFR(s): 493.1254(a)(2)

(a)(2) Function checks as defined by the manufacturer and with at least the frequency specified by the manufacturer. Function checks must be within the manufacturers established limits before patient testing is conducted. (b) Equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer. The laboratory must do the following:

This STANDARD is not met as evidenced by:

Based on observation of the laboratory and interview with the technical supervisor (TS) and testing personnel (TP), the laboratory failed to perform function checks as defined by the manufacturer for 2 of 2 Thermofisher Traceable thermometers in use. Findings: 1. Observation of the laboratory on June 15, 2026 at 3:15 pm revealed, two

Thermofisher Traceable thermometers (S/N: 240427535 and S/N: 240428047) in use both with function check due dates of May 24, 2026. 2. By interview on June 15, 2026 at 3 3:20 pm, the TS and TP were unaware that the thermometers had to be checked for periodic functionality.

D5793

ANALYTIC SYSTEMS QUALITY ASSESSMENT

CFR(s): 493.1289(b)(c)

(b) The analytic systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of analytic systems quality assessment reviews with appropriate staff. (c) The laboratory must document all analytic systems assessment activities.

This STANDARD is not met as evidenced by:

Based on review of Quality Assurance Plan (QAP), lack of documented quality assurance (QA) activities and interview with technical supervisor (TS) and testing personnel (TP), the laboratory failed to assess and document analytical system activities performed for 2 of 2 years (June 2024 to June 2026). Findings: 1. The Quality Assurance Plan stated, "The QA program is designated to: - Evaluate the effectiveness of the laboratory policies and procedure - Identify and correct problem - Ensure accurate, reliable and prompt reporting of test results - Ensure the adequacy and competency of the laboratory staff - Meet all regulatory requirements and they apply to the services offered" 2. The above plan did not address ongoing QA activities for analytical systems as required by 493.1251 through 493.1283. 3. The laboratory failed to provide documentation of all analytical system QA activities performed for 2 years (June 2024 to June 2026). 4. In an interview on June 15, 2026 at 2:00 pm, the TS and TP confirmed the above findings.

D5893

POSTANALYTIC SYSTEMS QUALITY ASSESSMENT

CFR(s): 493.1299(b)(c)

(b) The postanalytic systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of postanalytic systems quality assessment reviews with appropriate staff. (c) The laboratory must document all postanalytic systems quality assessment activities.

This STANDARD is not met as evidenced by:

Based on review of Quality Assurance Plan, lack of documented quality assurance (QA) activities and interview with technical supervisor (TS) and testing personnel (TP), the laboratory failed to assess and document postanalytical system activities performed for 2 of 2 years (June 2024 to June 2026). Findings: 1. The Quality Assurance Plan stated, "The QA program is designated to: - Evaluate the effectiveness of the laboratory policies and procedure - Identify and correct problem - Ensure accurate, reliable and prompt reporting of test results - Ensure the adequacy and competency of the laboratory staff - Meet all regulatory requirements and they apply to the services offered" 2. The above plan did not address ongoing QA activities for post analytical systems as required in 493.1291. 3. The laboratory failed to provide

documentation of all postanalytical system QA activities performed for 2 years (June 2024 to June 2026). 4. In an interview on June 15, 2026 at 2:00 pm, the TS and TP confirmed the above findings.