Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	21D0957235	06/22/2022
Name of Provider or Supplier	**Street Address, City, State**	
Immunopathogenesis Section	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	The Centers for Medicare and Medicaid Services (CMS) Federal Surveyor conducted an announced routine CLIA recertification survey at the Immunopathogenesis Section on June 22, 2022. The laboratory was surveyed under 42 CFR part 493 CLIA regulations. The follwoing deficiencies were found during the announced routine CLIA recertification survey:
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) 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. This STANDARD is not met as evidenced by: Based on review of the Quality Assurance Plan, alternative proficiency testing (PT) records and interview with the testing personnel (TP), the laboratory failed to verify the accuracy of the Anticytokine Autoantibody Screening test at least twice annually. Findings include: 1. The Quality Assurance Plan, Accuracy Tests and Competency Checks states, "A blind previously tested specimen is repeated to ensure the accuracy of the test results and serves as an accuracy for CLIA twice a year." 2. On the day of survey, June 22, 2022 at 1:55 pm, review of PT records revealed, the laboratory verifies the accuracy of the Anticytokine Autoantibody Screening test once a year. 3. The TP and the laboratory director confirmed the Anticytokine Autoantibody Screening Test has not been performed at least twice annually on June 22, 2022 around 3:30 pm.
D6094	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to

	identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on review of the Quality Assurance (QA) Plan, lack of Laboratory Checklist reviews and interview with the testing personnel (TP), the laboratory director failed to ensure the QA Plan was maintained and reviewed annually in 2020 and 2021. Findings include: 1. The Quality Assurance Plan, states, "The QA plan is reviewed annually to detect problems as they occur." 2. On the day of survey, June 22, 2022 around 2:10 pm, review of the QA plan and laboratory checklist revealed, the laboratory has established a plan to assure the quality of laboratory testing and to identify failures as they occur. 3. The TP could not provide documentation of annual laboratory checklist reviews that assess the laboratory's general, pre- analytical, analytical and post analytical processes. 4. The TP and the laboratory director confirmed the the annual reviews were not performed on June 22, 2022 around 3:30 pm.