Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	31D0703239	06/22/2021
Name of Provider or Supplier	**Street Address, City, State**	
Allergy And Arthritis Associates	600 Mt Pleasant Avenue Suite C, Dover, NJ	

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
D5433	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(1) For 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 establish a maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. The laboratory must perform and document the maintenance activities specified in paragraph (b)(1)(i) of this section. This STANDARD is not met as evidenced by: Based on lack of Microscope Maintenance Records (MMR), Procedure Manual (PM) and interview with the Technical Supervisor (TS), the laboratory failed to establish a maintenance protocol for the microscope from 11/29/18 to the date of the survey. The TS confirmed on 6/22/21 at 1:30 pm that the laboratory did not establish a maintenance protocol for the microscope.
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 surveyor review of the laboratory Procedure Manual (PM) and interview with the Technical Supervisor (TS) , the Laboratory Director (LD) failed to ensure a Quality Assurance (QA) program was accurately established to assure quality of

	laboratory services for Hematology and Chemistry tests provided from 11/19/18 to the date of the survey. The finding includes: 1. The QA procedure did not include a review that patient Work Records (WR) were accurately scanned into the patients Electronic Medical Record (EMR). 2. The TS confirmed on 6/22/21 at 2:45 pm that a QA program was not accurately established.