Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	49D2106069	06/15/2022
Name of Provider or Supplier	**Street Address, City, State**	
Inova Laboratories At Fair Oaks	3580 Joseph Siewick Drive, Fairfax, VA	

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 announced CLIA recertification survey was conducted at Inova Laboratories at Fair Oaks on June 15, 2022 by the Virginia Department of Health's Office of Licensure and Certification. The laboratory was surveyed under 42 CFR part 493 CLIA Requirements. Specific deficiencies cited are as follows:
D2007	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods This STANDARD is not met as evidenced by: Based on review of the laboratory's Centers for Medicare and Medicaid Services Laboratory Personnel Report form (CMS 209), proficiency testing (PT) records, lack of documentation, and an interview, the laboratory failed to rotate 13 of 13 PT events (hematology, coagulation, and chemistry) among testing personnel (TP) in calendar year 2021. Findings include: 1. Review of the CMS 209 laboratory personnel form revealed that the laboratory director identified TP A and TP B as responsible for moderate/high complexity hematology, coagulation, and chemistry patient testing. (See attached Testing Personnel Code Sheet.) 2. Review of the laboratory's 2021 College of American Pathologists (CAP) hematology, chemistry, and coagulation PT documentation, a total of thirteen (13) events, revealed that TP A signed attestation /performed: 2021 WB Prothrombin Time/INR Events WP3-A, B, C; 2021 General Chemistry Events A, B, C; 2021 Reticulocyte Events RT A, B; 2021 Hematology Auto Differential Events FH9 Events A, B, C; 2021 Clinical Microscopy Events CM-A, B; TP A performed 13 of 13 events reviewed in calendar year 2021. The inspector requested to review PT rotation including TP B during calendar year 2021. No documentation was available for review. 3. An exit interview with the technical supervisor on 6/15/22 at approximately 12:30 PM confirmed the above findings.

D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on a tour, review of policies, hematology analyzer performance verification records, lack of documentation, and an interview, the laboratory failed to record an evaluation/verification of precision and reportable range for Sysmex XN-1000 Complete Blood Count (CBC) testing after a physical move/installation to a new suite in February 2022 prior to reporting four thousand four hundred nineteen (4,419) patient test results as of the date of the inspection on June 15, 2022. Findings include: 1. During a tour of the laboratory on 6/15/22 at approximately 10:00 AM, the inspector noted that the laboratory had physically moved from a fourth level downstairs to a first floor suite location. The inspector inquired of the move date. The technical supervisor (TS) stated: "We moved from upstairs earlier this year on February 17, 2022." 2. Review of the laboratory policies revealed a Calibration Verification policy that outlined: "Calibration verification and AMR validation are performed under following circumstances - with every methodology installation, when instructed by the manufacturer, when a major instrument part is changed or after major preventative maintenance, when QC trends or shift necessitating, or if instrument is moved." 3. Review of the Sysmex XN-1000 analyzer's performance verification documentation (serial number 22415) revealed no lab director approved evaluation/verification of CBC precision or reportable for the timeframe of the installation in the new laboratory location (2/17/22) up to the date of the inspection, 6/15/22. The inspector requested the performance records. No documentation was available for review. 4. Review of the patient test logs revealed that the lab had resulted 4,419 CBC reports during the four months outlined above. 5. An exit interview with the TS on 6/15/22 at approximately 12:30 PM confirmed the above findings