

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 49D2077851	(X3) Date Survey Completed 09/18/2018
Name of Provider or Supplier Inova Fairfax Hospital Gainesville Vein & Vascular	Street Address, City, State 13575 Heathcote Boulevard - Suite 200, Gainesville, 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 Fairfax Hospital Gainesville Vein and Vascular on September 18, 2018 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	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>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</p> <p>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, and interview, the laboratory failed to rotate proficiency testing among the personnel performing patient testing for ten (10) of twelve (12) events from October 2016 to September 2018. Findings include: 1. Review of the CMS 209: Laboratory Personnel form revealed three (3) laboratory testing personnel listed as performing patient testing. (See attached Testing Personnel Code Sheet.) 2. Review of the American Proficiency Institute (API) proficiency testing records from October 2016 to September 2018 (12 events) revealed that Testing Personnel A (TP A) performed the following PT events: 2016 Event 3 Chemistry Core, 2017 Event 1 Hematology /Coagulation, 2017 Event 2 Chemistry Core, 2017 Event 2 Hematology/Coagulation, 2017 Event 3 Chemistry Core, 2017 Event 3 Hematology/Coagulation, 2018 Event 1 Chemistry Core, 2018 Event 1 Hematology/Coagulation, 2018 Event 2 Chemistry Core, 2018 Event 2 Hematology/Coagulation, a total of ten (10) events. 3. In an exit</p>

interview with Testing Personnel B (TP B) at approximately 11:45 AM, it was confirmed that the laboratory failed to rotate PT among all personnel responsible for performing patient testing for the events and timeframe outlined above.