Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	49D0896192	01/23/2019
Name of Provider or Supplier	**Street Address, City, State**	
Inova Hematology Oncology	8501 Arlington Boulevard - Suite 340, 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 Hematology Oncology on January 23, 2019 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:
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 review of performance verification records, and an interview, the laboratory failed to verify reference (normal) ranges for Complete Blood Cell counts (CBC) performed on the Sysmex 1000i hematology analyzer prior to reporting patient results from November 13, 2017 until January 23, 2019. Findings include: 1. Review of the laboratory's Sysmex 1000i (serial number 63495 installed 10/14/17) hematology analyzer's performance verification documentation revealed the documentation did not include verification of the reference (normal) ranges for CBCs prior to patient testing on November 13, 2017. When requested, the laboratory provided no reference range verification documentation for review. 2. An interview with testing personnel B at approximately 11:30 AM confirmed the findings above.
D6128	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(9)

	The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least annually after the first year, unless test methodology or instrumentation changes, in which case, prior to reporting patient test results, the individual's performance must be reevaluated to include the use of the new test methodology or instrumentation. This STANDARD is not met as evidenced by: Based on the review of the CLIA Laboratory Personnel Report Form (CMS-209 Form), testing personnel (TP) records, and an interview, the technical supervisor (TS) failed to perform the annual competency assessment for one (1) of three (3) TP in 2017 and 2018. Findings include: 1. Review of the CMS-209 Form revealed the laboratory director (LD) performs the duties of the TS and TP B performs patient testing (See attached personnel code sheet). 2. Review of TP B's personnel records revealed no documentation of annual competency assessment in 2017 and 2018. 3. An interview with TP B at approximately 10:00 AM confirmed the findings above.