Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	49D2136613	07/25/2018
Name of Provider or Supplier	**Street Address, City, State**	
Hematology Oncology Associates Of Fredericksburg	125 Woodstream Blvd, Stafford, 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 initial survey was conducted at Hematology Oncology Associates of Fredericksburg on July 25, 2018 by the Virginia Department of Health's Office of Licensure and Certification. The laboratory was surveyed under 42 CFR part 493 CLIA Regulations. 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 the laboratory's performance verification records and interviews, the laboratory failed to verify reference (normal) ranges for Complete Blood Cell counts (CBC) performed on the Sysmex XN-L hematology analyzer prior to reporting patient results from May 8, 2018 until July 26, 2018. Findings include: 1. Review of the laboratory's Sysmex XN-L (serial number 11008, installed 5/8/18) hematology analyzer's performance verification documentation revealed the documentation did not include verification of the reference (normal) ranges for CBCs after the instrument was installed. The surveyor requested to review documentation that the laboratory evaluated and verified the reference (normal) ranges for the Sysmex XN-L prior to patient testing. The laboratory provided no documentation for review. 2. An interview with the Technical Consultant and Testing Personnel A at approximately 10:30 AM,

	confirmed that the laboratory failed to document the verification of the normal ranges for CBCs performed on the Sysmex XN-L analyzer prior to patient testing that began in May 2018.