Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	49D2234706	06/01/2022
Name of Provider or Supplier	**Street Address, City, State**	
Virginia Cancer Specialists Pc	210 W Shirley Ave Suite 111, Warrenton, 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 Virginia Cancer Specialists on 06/01/22 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:
D6029	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(11) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results. This STANDARD is not met as evidenced by: Based on the review of the Laboratory Personnel Report Form (CLIA) (CMS-209 Form), initial performance verification records, testing personnel (TP) records and interviews, the laboratory director failed to ensure that five of five TP had documented training assessments prior to performing patient testing procedures for hematology on 10/25/21. Findings include: 1. Review of CLIA CMS-209 form revealed that there are five TP (A-E) performing patient testing in the subspecialty of hematology (See attached TP Code Sheet). 2. Review of the initial performance verification records for the Sysmex XN 550 hematology analyzer (serial number 22630) revealed the installation procedures performed on 10/13/21 and a "go live" date for patient testing on 10/25/21. 3. Review of five TP (A-E) records and an interview with the technical consultant and lab manager on 06/01/22 at approximately 11:30 AM revealed that the lab is a new site for the organization. The inspector

	requested to review training documentation for the TP for the new site. In concurrence, the technical consultant and lab manager stated, "the affiliated sites use the same manufacturer Sysmex with similar instrumentation. The only exception for this lab is that this analyzer has a front loader, an automated specimen loader. We do not have training documents for this analyzer because we use the same Sysmex manufacturer in our other sites." The training documents were not available for review. 4. An exit interview with the lab manager and technical consultant on 06/01 /22 at approximately 12:00 PM confirmed the findings.