

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 49D2136613	(X3) Date Survey Completed 11/05/2019
Name of Provider or Supplier Hematology Oncology Associates Of Fredericksburg	Street Address, City, State 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 recertification survey was conducted at Hematology Oncology Associates of Fredericksburg on November 5, 2019 by the Virginia Department of Health's Office of Licensure and Certification. The laboratory was surveyed under 42 CFR part 493 CLIA Regulations. The specific deficiencies are as follows:
D5407	<p>PROCEDURE MANUAL CFR(s): 493.1251(d)</p> <p>Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's policy and procedure manual, Medica EasyRA chemistry analyzer validation records and interview with the Technical Consultant (TC), the Laboratory Director (LD) failed to approve, sign and date the written procedure for the Medica EasyRA chemistry analyzer prior to reporting patients from August 17, 2019 until the date of the survey on November 5, 2019. Findings include: 1. Review of the policy and procedure manual revealed a lack of a procedure for the Medica EasyRA chemistry analyzer. In an interview with the TC, he/she stated they have a procedure but it was not signed by the LD. The TC provided an EasyRA procedure that was not signed and dated by the LD for the surveyor's review. 2. Review of the Medica EasyRA (serial number 08107609) validation records (signed by the LD on August 8, 2019) revealed the instrument was installed on July 7, 2019 and patient testing began on August 17, 2019. 3. In an exit interview with the TC at approximately 1:45 PM, the TC confirmed the findings.</p>