Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	49D2097462	04/11/2019
Name of Provider or Supplier	**Street Address, City, State**	
Carilion Clinic Family Medicine- Oakgrove	1818 Electric Rd, Roanoke, 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 the Carilion Clinic Family Medicine- Oak Grove on April 11, 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:
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. This STANDARD is not met as evidenced by: Based on an interview with the technical consultant, quality control (QC) records, lack of documentation, and policy and procedures (P&P), the laboratory failed to retain the manufacturer's assay sheets for acceptable ranges and the end of lot statistical analysis for seven (7) of seven (7) CDS Boule Con-diff hematology QC materials utilized from January 1, 2017 and up to August 31, 2018. Findings include: 1. An interview with the technical consultant at approximately 9:30 AM revealed that the laboratory utilizes the CDS Boule Con-diff hematology QC materials to perform daily QC procedures. The technical consultant revealed that the manufacturer assay sheets and end of the lot statistical analysis for 7 of the 7 lot numbers were not retained during intra-office moving of records. 2. Review of the daily QC records for the CDS Medonic CA 620 hematology analyzer revealed the following lot numbers and lack of documentation for the manufacturer assay sheets and end of the lot statistical analysis from January 1, 2017 and up to August 31, 2018: Lot number 2161121, 2161122 and 2161123, Lot number 2170221, 2170222 and 2170223, Lot number 2170521, 2170522 and 2170523, Lot number 2170821, 2170822 and 2170823, Lot number 2171121, 2171122 and 2171123, Lot number 2180231, 2180232 and 2180233 and, Lot number 2180531, 2180532 and 2180533. Total of 7 lot numbers. 3. Review of

	P&P revealed the following statement: "Quality Control (signed by lab director 8 /2018)- Documentation proving the accuracy of the analytical system are reviewed by the laboratory director or designee and maintained in writing for the staff and representative of approved regulatory agencies." 4. During the exit interview at approximately 11:45 AM, the technical consultant confirmed the findings.