

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 49D2097462	(X3) Date Survey Completed 06/28/2023
Name of Provider or Supplier Carilion Clinic Family Medicine- Oakgrove	Street Address, City, State 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-Oakgrove on 06/28/23 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:
D5429	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1)</p> <p>For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.</p> <p>This STANDARD is not met as evidenced by: Based on the review of the manufacturer operator's guide, lack of documentation, and interview, the lab failed to perform and document the monthly maintenance for the hematology analyzer for 14 of 20 months reviewed. Dates of record review include 10 /01/23 up to 05/31/23. Findings include: 1. Review of the manufacturer operator's guide revealed instructions for performing monthly cleaning procedures utilizing the Boule Cleaning Kit (cleaning procedure and clot prevention) listed under "Section 8: Cleaning, Maintenance & Transport", "8.2 Monthly Cleaning". 2. Review of the available maintenance records for the Medonic M-series analyzer revealed lack of documentation of the performance of the monthly maintenance for 14 of 20 months reviewed: November, December 2021; January, May-November 2022; and January, March-May 2023. The inspector requested to review aforementioned documents. The documents were not available for review. 3. An exit interview with the technical consultant and primary testing personnel on 06/28/23 at 11:15 AM confirmed the findings.</p>