

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 49D0231750	(X3) Date Survey Completed 03/14/2022
Name of Provider or Supplier Carilion Clinic Fm-Daleville	Street Address, City, State 150 Market Ridge Lane, Daleville, 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-Daleville on 03/14/22 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: The laboratory is performing COVID-19 testing and is in compliance with the applicable COVID-19 reporting requirements.
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 11 of 12 months reviewed in 2021. 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 (serial number 46469) revealed lack of documentation of the performance of the monthly maintenance for 11 of 12 months reviewed in 2021. 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 03/14/22 at 1215 confirmed the findings.</p>
D6053	<p>TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9)</p>

The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens.

This STANDARD is not met as evidenced by:

Based on the review of Laboratory Personnel Report Form (CLIA) (CMS-209 Form), testing personnel (TP) records, lack of documentation, and interview with the technical consultant (TC), the TC failed to perform and document the semi-annual competency assessment for one (1) of 1 new TP in 2021. Findings include: 1. Review of the CMS-209 form revealed that TP A was trained and performing patient testing on 01/12/21. See attached TP code sheet. 2. Review of TP A records revealed lack of documentation by the TC of performance and review of the semi-annual competency assessment. No other documented competency assessment was available for review upon request. 3. An exit interview with the TC on 03/14/22 at approximately 1215 confirmed that the findings.