

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 49D0231758	(X3) Date Survey Completed 08/10/2021
Name of Provider or Supplier Carilion Clinic Family Medicine - Dublin	Street Address, City, State 118 Broad Street, Dublin, 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- Dublin on August 10, 2021 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	<p>RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on a review of quality control (QC) records, lack of documentation, and interview with the primary testing personnel (TP), the laboratory failed to retain the "CDS Boule Con-Diff" hematology quality control (QC) manufacturer's assay information inserts documenting Complete Blood Cell (CBC) count QC acceptable ranges for six (6) of 6 lot numbers utilized from June 3, 2019 up to October 31, 2020. Findings include: 1. Review of the laboratory's end of the QC lot instrument printouts from June 3, 2019 up to October 31, 2020 revealed the laboratory received and utilized 6 lot numbers of the "CDS Boule Con-Diff" hematology QC materials. The following QC lacked documentation of acceptable ranges or manufacturer's package inserts at the date of survey: Lot number- 2190531, 2190532, 2190533, Lot number- 2190831, 2190832, 2190833, Lot number- 2191121, 2191122, 2191123, Lot number- 2200221, 2200222, 2200223, Lot number- 2200521, 2200522, 2200523 and, Lot number- 2200821, 2200822, 2200823. 2. An exit interview with the primary TP on 08/10/21 at approximately 12:00 PM confirmed the findings. A phone exit interview with the technical consultant on 08/10/21 at approximately 3:30 PM confirmed the findings.</p>

D6053**TECHNICAL CONSULTANT RESPONSIBILITIES**

CFR(s): 493.1413(b)(9)

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 two (2) of 2 new TP. Dates of record review include 06/03/19 up to 08/10/21. Findings include: 1. Review of the CMS-209 form revealed that TP A and B was trained and performing patient testing on 05/27/20 and 07/15/20, respectively. See attached TP code sheet. 2. Review of TP A and B records revealed lack of documentation by the TC of performance and review of the semi-annual competency assessments. 3. During a phone exit interview with the TC on 08/10/21 at approximately 3:30 PM, the documentation was not available for review and the above-specified findings were confirmed.