Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 49D0226114	(X3) Date Survey Completed 06/04/2025
Name of Provider or Supplier Carilion Clinic Fm -Waynesboro	**Street Address, City, State** 428 S Magnolia Avenue, Waynesboro, 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 Carilion Clinic Family Medicine - Waynesboro on June 4, 2025 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 and includes the Condition under 42 CFR part 493 CLIA Regulation: D2000 - 42 C.F.R. 493-801 Condition: Enrollment and Testing of Samples.
D2000	ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801 Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994. This CONDITION is not met as evidenced by: Based on a review of the Centers for Medicare and Medicaid Services CASPER 0096D CLIA Application and Survey Summary Report (CMS CASPER 0096D), a tour, proficiency testing (PT) records, patient logs, lack of documentation, and interviews, the laboratory failed to enroll in a hematology PT program for Complete Blood Count (CBC) for five (5) of twenty-three months reviewed while reporting five hundred sixty-one (561) patient CBC panels in 2025 year to date. (Note: survey timeframe: 7/7/23 - 6/4/25, timeframe of non enrollment: 1/1/25-6/4/25). Findings include: 1. Review of the CASPER 0096D report during pre-survey preparation revealed a lack of hematology PT scores reported for the following speciality and related analytes in calendar year 2025: 0760 HEMATOLOGY - Speciality 0765 Cell

	Identification / WBC Differential 0775 Red Blood Cell Count, RBC 0785 Hematocrit, HCT 0795 Hemoglobin, HGB 0805 While Blood Cell Count, WBC 0815 Platelets, PLT 2. During a tour of the laboratory on 6/4/25 at 10 AM, the inspector noted one bench top Sysmex XN-L hematology analyzer. The inspector inquired regarding the operation of the analyzer and the lead tech stated at 10:00 AM, "We have not run CBC's in the last couple of weeks. We have been sending them out." 3. Review of the laboratory's 2024-2025 Wisconsin State Laboratory of Hygiene (WSLH) PT records revealed three hematology events (2024 Events 1-3). No hematology PT records for calendar year 2025 to date (6/4/25) were available. The inspector inquired regarding the lack of PT documentation for Event 1 of 2025 for their Sysmex CBC patient testing. The lead tech stated on 6/4/25 at 1 PM, "Our upper management sent in the PT enrollment for 2025. I was not aware or informed that CBC was not included". The technical consultant (TC) added by statement on 6/4/25 at 1 PM, "I noted that we did not have the 2025 PT records while preparing for this inspection. There was a miscommunication regarding enrollment for hematology between corporate and office laboratory staff." 4. The inspector requested the WSLH PT Enrollment Confirmation documentation. The record (dated 10/24/24) revealed the following PT modules were ordered for 2025 (order number 10034708): Cardiac Markers, INR - CoaguChek, Sedimentation Rate, Point of Care / PPMP Package, Mono Immunoserology, and SARS / Viral Molecular. 5. Review of patient test logs revealed the following number of CBC panels assayed on the Sysmex analyzer in calendar year 2025 year to date: January - 91; February - 74; March - 113; April - 142; May - 141; a total of 561 patient CBC panels were reported while not enrolled for regulated hematology analytes' PT module for 2025. 6. An interview with the lead testing personnel and TC on 6/6/25 at 1:30 PM confirmed the above findings.
D6015	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4) (e)(4) Ensure that the laboratory is enrolled in an HHS approved proficiency testing program for the testing performed and that-- This STANDARD is not met as evidenced by: Based on a review of the Centers for Medicare and Medicaid Services CASPER 0096D CLIA Application and Survey Summary Report (CMS CASPER 0096D), a tour, proficiency testing (PT) records, lack of documentation, hematology quality control (QC), instrument maintenance, patient test logs, and interviews, the laboratory director (LD) failed to ensure that the laboratory enrolled in a PT program for six of six hematology analytes: White Blood Cell Count (WBC), Red Blood Cell Count (RBC), Hemoglobin (HGB), Hematocrit (HCT), Platelet Count (PLT), and WBC Differential /Cell Identification (Cell ID) from 1/1/25 up to the date of the inspection on June 4, 2025. (Cross Reference D2000.) Findings include: 1. Review of the CMS CASPER 0096D report revealed a lack of PT scores for six of six hematology Complete Blood Count (CBC) analytes: WBC, RBC, HGB, HCT, PLT, and WBC Differential/Cell ID during calendar year 2025 to date of inspection, 6/4/25. 2. During a tour of the laboratory on 6/4/25 at 10 AM, the inspector noted a bench top CBC Sysmex XN-L hematology analyzer. 3. Review of laboratory's Wisconsin State Laboratory of Hygiene (WSLH) hematology PT records, a total of three events (2024 Events 1-3), revealed no records of an expected 2025 WSLH Event 1 for the hematology speciality analytes outlined above. The inspector requested to review 2025 PT Event 1 documentation. The records were not available for review. 4. Review of the 2025 Sysmex XN-L hematology maintenance, QC, and patient test logs

	revealed that the laboratory operated the analyzer for resulting patient CBC panels for the following five months in calendar year 2025 year to date: January, February, March, April, and May. 5. An interview with the lead testing personnel and Technical Consultant on 6/6/25 at 1:30 PM confirmed the above findings.