| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
|---|---|---|
| | 49D0972412 | 05/19/2026 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Carilion Clinic Fm-West Salem | 1935 West Main Street, Salem, 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 (FM)-West Salem on May 19, 2026 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: |
| **D2007** | TESTING OF PROFICIENCY TESTING SAMPLES<br>CFR(s): 493.801(b)(1)<br><br>(b)(1) The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods.<br><br>This STANDARD is not met as evidenced by:<br>Based on a review of the Centers for Medicare and Medicaid Services Laboratory Personnel Report form (CMS 209), proficiency testing (PT) records and interview, the laboratory failed to rotate hematology PT among testing personnel (TP) performing Complete Blood Count (CBC) patient testing by having one of five TP perform five of six modules during the 25 months reviewed (timeframe April 11, 2024 to May 19, 2026). Findings include: 1. Review of the CMS 209 form revealed that the laboratory director identified five TP who were qualified and performed CBC patient testing on the Medonic M Series hematology analyzer during the 25 months of review. 2. Review of the laboratory's Wisconsin State Laboratory of Hygiene (WSLH) PT records (2024 Events 2-3, 2025 Events 1-3, 2026 Event 1) a total of six events, revealed that TP A performed/signed attestations for the following CBC modules: WSLH 2024 Event 2 WSLH 2024 Event 3 WSLH 2025 Event 2 WSLH 2025 Event 3 WSLH 2026 Event 1 TP A performed five of six events reviewed (See Personnel Code Sheet). 3. An interview with the technical consultant on 5/19/26 at 12 PM confirmed the above findings. |
| **D5791** | ANALYTIC SYSTEMS QUALITY ASSESSMENT |

CFR(s): 493.1289(a)(c)

(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283.

This STANDARD is not met as evidenced by:
Based on a review of proficiency testing (PT) records, procedures, manufacturer's user guide, statistical quality control (QC) reports, lack of documentation, and interviews, the laboratory failed to ensure their monthly monitoring of control failures, shifts, and trends followed their procedure and manufacturer's user guide for patient Complete Blood Count (CBC) testing for 25 of 25 months reviewed (survey timeframe: April 11, 2024 - May 19, 2026). Findings: 1. During a review of the laboratory's PT records, the inspector noted that on their 2025 Wisconsin State Laboratory of Hygiene (WSLH) Hematology Event 1 that the laboratory received a score of 80 percent for Hematocrit (HCT). WSLH scored the five HCT challenges as: AT 1 reported 37.2 (acceptable range 36.7-39.7) AT 2 reported 36.8 (acceptable range 36.7-39.7) AT 3 reported 15.8 (acceptable range 15.5-16.7) AT 4 reported 15.1 (acceptable range 15.5-16.7) --noted as unacceptable AT 5 reported 50.4 (acceptable range 50.3-54.5) The inspector noted that the laboratory's HCT scores were shifted low in comparison to acceptable range (assayed on 2/5/25) . The inspector noted a "PT Failure Correction Action Worksheet" attached to the CBC PT module (completed on 8/28/25) and a TP had documented on the corrective action worksheet "unable to determine" (under the WSLH prompt Summarize the Source of PT Failure). 2. Review of the laboratory's Medonic M Series CBC procedure revealed the following instructions: Section Quality Control - "Out of range controls should be examined in comparison to evaluate if a pattern is indicated, and if so, the issue should be resolved." 3. The Medonic User Guide included under section 6.1 Quality Control, flow chart instructions to print weekly, monthly QC, data log print All Sample Reports. The inspector noted that the user guide also included instructions to press either Exclude or Include prompt to include outliers for QC evaluation. 4. Review of the laboratory's LJ QC monthly charts for the timeframe of 4/11/24 - 5/19/26 revealed no All Sample Reports statistical data that would include QC outliers for the reported CBC parameters (White Blood Cell, Red Blood Cell, Hemoglobin, HCT, Platelet, Mean Corpuscular Hemoglobin, Mean Corpuscular Volume and Concentration, White Blood Cell 3 Part Differential). 5. The inspector requested to review the All Sample Reports statistics for the survey timeframe. The reports were not available. The inspector inquired regarding the reason the LJ charts excluded outliers and how the laboratory was monitoring control failures, shifts, and trends without including the All Sample Reports statistics. The TC stated on 5/19/26 at 11:30 AM, "I will check with the laboratory for how they are printing the QC". The TC stated during a follow up offsite interview on 5/20/26 at 4:30 PM, "The limitation in the QC/LJ review is related to the printed report not displaying all data points needed to fully assess shifts and trends. I spoke with the service engineer, who walked us through an alternate method for printing QC reports using the [EXCLUDE/INCLUDE] button to manually select so all data appears." 6. Interviews with the TC on 5/19/26 at 12 PM and on 5/20 /26 at 4:30 PM and confirmed the above findings.