

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 49D0231426	(X3) Date Survey Completed 11/19/2024
Name of Provider or Supplier Carilion Childrens Pediatric Medicine - Postal	Street Address, City, State 4040 Postal Drive, 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 Carilion Children's Pediatric Medicine-Postal on November 19, 2024 by the Virginia Department of Health's Office of Licensure and Certification. The laboratory was surveyed under 42 CFR part 493 CLIA Requirements. Specific deficiency cited is as follows:
D2015	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6)</p> <p>(5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event.</p> <p>This STANDARD is not met as evidenced by: Based on a review of proficiency testing (PT) records, lack of documentation, and interviews, the laboratory failed to retain copies of attestation statements signed by the testing personnel (TP) and analyzer printouts for ten (10) of 10 challenge samples for two (2) of five (5) hematology PT testing events reviewed (survey timeframe: December 2022 to the date of the inspection on November 19, 2024). Findings include: 1. Review of the laboratory's Wisconsin State Laboratory of Hygiene (WSLH) PT documentation, a total of 5 events (2023 Events 1-3, 2024 Events 1-2), revealed no TP signed attestation records or Complete Blood Count (CBC) analyzer print outs retained for the following 2 events: 2023 WSLH Heme Event 1 (challenge samples 01-05), 2023 WSLH Heme Event 2 (challenge samples 06-10). 2. The</p>

inspector requested to review the attestation documentation and analyzer print outs for the events and CBC challenge samples outlined above. The documentation was not available for review. The technical consultant (TC) stated on 11/19/24 at 3:30 PM, "The PT notebook disappeared at some point in late 2023 or early 2024. It was an oversight that we did not get the instrument print outs back into the records." 3. An exit interview with the TC and lab director on 11/19/24 at 4:45 PM confirmed the above findings.