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| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number 49D0881952 | (X3) Date Survey Completed 10/07/2025 |
| Name of Provider or Supplier Smith Mountain Lake Family Practice Pc | Street Address, City, State 70 Westwind Road, Moneta, 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 |
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| D0000 | An announced CLIA recertification survey was conducted at Smith Mountain Lake Family Practice on October 7, 2025 by the Virginia Department of Health's Office of Licensure and Certification. The laboratory was surveyed under 42 CFR part 493 CLIA Regulations. Specific deficiency cited is as follows: |
| D2014 | <p>TESTING OF PROFICIENCY TESTING SAMPLES</p> <p>(b)(6) 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.</p> <p>This STANDARD is not met as evidenced by: Based on a review of Centers for Medicare and Medicaid Services Laboratory Personnel Report form (CMS 209), proficiency testing (PT) records, lack of documentation, and interviews, the laboratory failed to retain attestation statements signed by the laboratory director (LD) and testing personnel (TP) for five (5) of six (6) events reviewed (survey timeframe: January 18, 2024 to October 7, 2025). Findings include: 1. Review of the CMS 209 personnel form revealed that the LD identified two TP as responsible for performing non-waived hematology Complete Blood Counts (CBC) during the review timeframe of 1/18/24-10/7/25. 2. Review of the laboratory's Wisconsin State Laboratory of Hygiene (WSLH) hematology PT documentation (2024 Events 1-3, 2025 Events 1-3), a total of 6 events, revealed no signed LD or TP attestation statements for the following Complete Blood Count (CBC) modules: 2024 Event 1, 2024 Event 3, 2025 Event 1, 2025 Event 2, 2025 Event 3. 3. The inspector requested to review LD and TP attestation signatures for the</p> |

event listed above. The documentation was not available for review. The primary TP stated on 10/7/25 at 2:00 PM, "I was not aware that we had to sign attestations. I saw the forms in the packet but did not know they were necessary." 4. An interview with the primary TP and LD on 10/7/25 at 2:45 PM confirmed the above findings.