Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 49D0881952	**(X3) Date Survey Completed** 01/17/2024
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**
D0000	An announced CLIA recertification survey was conducted at Smith Mountain Lake Family Practice, PC on January 17, 2024 by the Virginia Department of Health's Office of Licensure and Certification. The laboratory was surveyed under 42 CFR part 493 CLIA Regulations. Specific deficiencies cited are as follows:
D1001	CERTIFICATE OF WAIVER TESTS CFR(s): 493.15(e) Laboratories eligible for a certificate of waiver must-- (1) Follow manufacturers' instructions for performing the test; and (2) Meet the requirements in subpart B, Certificate of Waiver, of this part. This STANDARD is not met as evidenced by: Based on a laboratory tour, review of quality control (QC) log book, procedures (manufacturer's user manual / package insert), analyzer onboard data files, lack of documentation, and interviews, the laboratory failed to follow manufacturer's instructions for Hemoglobin A1C QC verification during twelve (12) of 12 months in calendar year 2023. Findings include: 1. During a laboratory tour on 1/17/24 at 11:00 AM, the inspector noted one Abbott Alere Afinion AS100 in use for patient point of care Hemoglobin A1C testing. 2. During a review of the laboratory's hematology QC logs, the inspector noted Abbott Alere Afinion QC log sheets were included in the QC binder. The inspector noted QC log sheets for calendar years 2022 and 2024. The inspector noted no QC was recorded in calendar year 2023. 3. Review of the laboratory's procedures revealed an Abbott Alere Afinion manufacturer's user guide with the following instructions: A. "Use quality control materials to confirm that the analyzer and test kit are working properly"; B. "This is a CLIA waived test. If the laboratory modifies the test instructions, including quality control, the test will no longer meet the requirements of for waived categorization. A modified test is regarded as highly complex and applicable CLIA requirements."; C. "Control Testing - run QC with each new shipment/lot number, at least every 30 days, when training new testing

	personnel, and anytime an unexpected test result is obtained." 4. Review of the laboratory's procedures revealed an Abbott Afinion HbA1c Control package insert with the following instructions: "Quality control testing using Afinion HbA1c Control should be done to confirm that the Afinion Analyzer System is working properly and provides reliable results. Only when controls are used routinely and the values obtained are within acceptable ranges can accurate results for patient samples be assured. Frequency of control testing- controls should be analyzed with each new shipment of Afinion HbA1c Test kits, with each new test lot, at least every 30 days, when training new operators in correct use of the test kit and analyzer, anytime an unexpected test result is obtained. It is recommended to keep a permanent record of all quality control results. The Afinion Analyzer automatically stores the control results in a separate file record (consult the user manual)." 5. The inspector requested to review HbA1c QC log sheets for calendar year 2023. No additional records were available for review. The inspector and lead testing personnel (TP) reviewed the analyzer's onboard QC data logs and verified there were no QC files for 2023. The lead TP stated on 1/17/24 at 12:30 PM, "I realized while preparing for the inspection that we had not run QC last year. We had a change in staffing last year and it was overlooked." 6. An exit interview with the technical consultant and lead TP on 1/17 /24 at 1 PM confirmed the above findings.
D5437	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(a) Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (2) Using the criteria verified or established by the laboratory as specified in 493.1253(b)(3)-- (2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification. This STANDARD is not met as evidenced by: Based on a review of procedures, hematology calibration records, lack of documentation, and an interview, the laboratory failed to document calibration procedures every six (6) months for Complete Blood Count (CBC) testing according to the manufacturer's instructions during the twenty-three months reviewed (February 2022 to 1/17/24). Findings include: 1. Review of the laboratory's procedures revealed a Medonic M Series hematology analyzer user guide that outlined instructions to calibrate CBC testing on the analyzer at a frequency of every 6 months. 2. Review of the laboratory's Medonic instrument's CBC calibration records from February 2022 to the date of the inspection, 1/17/23, revealed calibration documentation on 6/21/22, 11 /21/22, 10/3/23, and 12/13/23. The inspector noted that a 6 month calibration would have been due in May 2023 and requested to review additional calibration records. No additional records were available for the eleven month timeframe between 11/21/22 and 10/3/23. 3. An exit interview with the technical consultant and lead testing personnel on 1/17/24 at 1 PM confirmed the above findings.