Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	49D2004750	09/15/2022
Name of Provider or Supplier	**Street Address, City, State**	
Blue Ridge Internal Medicine	1922 Thomson Drive - Suite B, Lynchburg, 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 the Blue Ridge Internal Medicine on 09/15/22 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:
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on a tour of the laboratory, review of policy and procedures (P&P), quality control (QC) records, lack of documentation, patient test data and interview, the lab failed to follow the established P&P of performing external QC materials every 30

	days for four of thirteen months reviewed from 06/01/21 up to the date of survey on 09 /15/22. Findings include: 1. A tour of the lab at approximately 10:15 AM on 09/15/22 revealed the lab assays the troponin and D-Dimer analytes on the Quidel Alere Triage instrument. 2. Review of the P&P revealed an Individualized Quality Control Plan (IQCP), approved by the lab director on 06/01/21, that defined performing external QC materials every 30 days for the abovementioned analytes. 3. Review of QC records and patient test data from 06/01/21 up to the date of survey on 09/15/22 revealed lack of documentation of external QC materials for the following months and analytes: July 2021- troponin and D-Dimer analytes, August 2021- troponin and D-Dimer analytes, October 2021- troponin and D-Dimer analytes, February 2022- troponin analyte. Patient test data reviewed in the Labtop Doc lab information system (LIS) revealed no patients were reported for the aforementioned months. 4. An exit interview with the Ancillary Services Manager and testing personnel on 09/15/22 at approximately 1245 confirmed the findings.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: Based on the Centers for Medicare and Medicaid Services CLIA Laboratory Application for Certification form (CMS 116), review of policy and procedures (P&P), calibration verification and linearity records, lack of documentation, and interviews, the lab failed to follow the established P&P of performing calibration verification procedures for the 21 chemistry analytes every six months in the calendar year 2021. Findings include: 1. Review of the CMS 116 application revealed the lab performs the following analytes on the Ace Alera Alfa Wassermann chemistry analyzer: Alamine aminotrasferease, albumin, alkaline phosphatase, bicarbonate, bilirubin total, calcium, chloride, cholesterol total, creatinine, glucose, potassium, sodium, protein total, triglycerides, urea nitrogen, uric acid, amylase, creatine kinase total, HDL cholesterol, iron, and lipase. 2. Review of the P&P revealed the following statement, "Ace Linearity- This policy states that Alera verification and linearity will be performed every 6 months. This is noted on the Quality Assurance yearly

	calendar." 3. Review of available calibration verification and linearity records revealed the lab utilizes the Audit MicroControl Linearity materials to perform the verifications and linearity procedures. In addition, the review revealed lack of documentation of the performance and review of the aforementioned procedures every six months in 2021 (performed on 01/04/21). The inspector requested to review additional verification and linearity procedures in 2021. The documentation was not available for review at the date of survey on 09/15/22. 4. An exit interview with the Ancillary Services Manager and testing personnel on 09/15/22 at approximately 1245 confirmed the findings.