Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 49D0662940	(X3) Date Survey Completed 10/02/2024
Name of Provider or Supplier Blue Ridge Urological Associates, Pc	**Street Address, City, State** 70 Medical Center Drive - Suites 208-212, Fishersville, 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 Validation survey was conducted at Blue Ridge Urological Associates on 10/02/2024 by the Virginia Department of Health's Office of Licensure and Certification. The laboratory was surveyed under 42 CFR part 493 CLIA Requirements. Specific deficiencies cited are as follows:
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on the review of Centers for Medicare and Medicaid Services CLIA Laboratory Application for Certification form (CMS 116), tour of the laboratory testing area, quality control and calibration records, lack of documentation, and interviews, the laboratory director failed to review and approve the accuracy, precision, and reportable range of two of three replacement Qualigen FastPack analyzers on 10/25/22 and 06/25/24, respectively. Findings include: 1. Review of the CMS 116 application and a tour of the laboratory testing area on 10/02/24 at 10:35 AM revealed the laboratory uses three Qualigen FastPack analyzers to perform Prostate Specific Antigen (PSA) assay testing. 2. Review of the quality control and calibration records for all three analyzers revealed that replacement analyzers were installed on 10/25/22 (serial number 0576) and 06/25/24 (serial number 0505). The record review also revealed that initial verification of accuracy, precision and reportable range for the

	replacement analyzers were performed on 10/25/22 and 06/25/24. The initial verification records lacked evidence of review and approval by the laboratory director. 3. In an interview with testing personnel #1 (TP #1) on 10/02/24 at 12:20, they stated, "we did have new instruments, and we performed the initial testing, but the lab director didn't sign the initial verification documents." 4. An exit interview with TP #1 on 10/02/24 at 13:15 confirmed the findings.
D5433	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(1) For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must establish a maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. The laboratory must perform and document the maintenance activities specified in paragraph (b)(1)(i) of this section. This STANDARD is not met as evidenced by: A. Based on tour of the laboratory testing area, the review of policy and procedures (P&P), pipette calibration records, lack of documentation, and interview, the laboratory failed to follow the established P&P for performing annual pipette calibration for two of four pipettes in the calendar year 2023. Findings include: 1. Tour of the laboratory testing area on 10/02/24 at 10:35 AM revealed the laboratory uses four Gilson 100 microliter (ul) pipettes for patient testing. 2. Review of the P&P "General Maintenance" revealed the following statement, "Pipette Maintenance b. Each pipette will be submitted to Gilson Services Center for annual recalibration." 3. Review of pipette calibration records revealed that two of the four pipettes lacked documentation of annual recalibration for the calendar year 2023: serial numbers SJ 06072 and PK 05596. 4. The surveyor requested to review the annual recalibration records for the above-specified pipettes during the survey. The documents were not available for review. 5. An exit interview with testing personnel #1 on 10/02/24 at 13: 15 confirmed the findings. B. Based on tour of the laboratory testing area, the review of policy and procedures (P&P), centrifuge records, lack of documentation, and interviews, the laboratory failed to follow the established P&P for performing annual revolutions per minute (RPM) checks for two of two StatSpin centrifuges for the calendar year 2023. Findings include: 1. Tour of the laboratory testing area on 10/02 /24 at 10:35 AM revealed the laboratory used two StatSpin centrifuges (serial numbers 115M50108051 and 547M50104724) to centrifuge patient samples for the Qualigen FastPack Prostate Specific Antigen assay. 2. Review of the P&P "General Maintenance" revealed the following statement, "Centrifuge Maintenance d. Centrifuge rpm's are checked annually by Shenandoah Medical Supply, Inc. Documentation of the centrifugation rpm validation is kept in this procedure manual." 3. Review of available RPM checks for both centrifuges revealed verification performed on 09/18/24. 4. In an interview with primary testing personnel #1 (TP #1) on 10/02/24 at 12:15, the surveyor requested documentation of the RPM checks for the calendar year 2023 and TP #1 stated that "they didn't perform those checks in 2023." 5. An exit interview with testing personnel #1 on 10/02/24 at 13:15 confirmed the findings.