

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 42D0726779	(X3) Date Survey Completed 11/27/2024
Name of Provider or Supplier Blue Ridge Urology Pa	Street Address, City, State 402 Memorial Drive Ext, Greer, SC	
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 onsite announced CLIA recertification survey was conducted on November 27, 2024, at the clinical laboratory of Blue Ridge Urology in Greer by the South Carolina Department of Public Health's (SC DPH) Bureau of Nursing Homes and Medical Services. The laboratory was found to be out of compliance with 42 CFR Part 493, CLIA Requirements for Laboratories. The following is a list of CONDITION and STANDARD LEVEL deficiencies cited:
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 the review of the Wisconsin State Laboratory of Hygiene (WSLH) Attestation statements, laboratory policy and procedure manual, and staff interview, the laboratory failed to ensure that all attestation statements are signed by the testing personnel (TP) and laboratory director (LD). Findings included: 1. Review of WSLH attestation statement documentation from 2022 through October 2024, 1 out of 40 events reveals lack of laboratory director's signature. 2. Review of WSLH Proficiency Testing documentation reveals that the 2024-MiscQA_POC2 lack of LD's signature. 3. Review of the laboratory policy and procedure manual reveals a lack of procedure</p>

for the handling, preparation, processing, examination, and each step in the testing and reporting for all proficiency testing samples 4. In an interview on 11/27/2024 at 1:00pm in the laboratory office with TP1, the findings were confirmed.

D2016

SUCCESSFUL PARTICIPATION
CFR(s): 493.803(a)(b)(c)

(a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history.

This CONDITION is not met as evidenced by:
Based on review of WSLH PT result documentation in the laboratory, WSLH PT result documentation from WSLH, and staff interview, the laboratory failed to successfully participate (minimum score of 80%) in a PT program approved by CMS. Findings included: 1. Review of the WSLH PT results from laboratory documentation reveals the following: a. Event: WSLH PT 2024-Bacti_Viral1 1. Failure: Lab report = UC-2 Organism ID Escherichia species Acceptable response = Staphylococcus saprophyticus 2. Failure: Lab report = UC-5 Organism ID Proteus species Acceptable response = Staphylococcus aureu b. Event: WSLH PT 2024-Bacti_Viral2 1. Failure: Lab report = UC-7 Organism ID Enterobacter species Acceptable response = Citrobacter freundii 2. Failure: Lab report = UC-8 Organism ID Escherichia species Acceptable response = Enterococcus faeciu 2. Review of WSLH performance summary reveals unsuccessful performance with failures of less than 80% for two consecutive PT events. a. Event: WSLH PT 2024-Bacti_Viral1 score = 77% b. Event: WSLH PT 2024-Bacti_Viral2 score = 67% 3. Review of the CASPER Report 0155D reveals: a. Event 1 for Bacteriology score = 77% b. Event 2 for Bacteriology score = 67% 4. In an interview on 11/27/2024 in the laboratory office at 2:00pm with TP1, the findings were confirmed.

D5209

PERSONNEL COMPETENCY ASSESSMENT POLICIES
CFR(s): 493.1235

As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.

This STANDARD is not met as evidenced by:

	<p>Based on review of the laboratory's policy and procedure manual, personnel files, and staff interview, the laboratory failed to establish and follow written policies and procedures to assess employee competency. Findings included: 1. Review of the laboratory policy and procedure manual reveals a lack of a written policy and procedure for the assessment of employee competency. 2. Review personnel files for 6 out of 6 testing personnel (TP) lack appropriate competency assessments (initial and semiannual). 3. In an interview on 11/27/2024 at 1:00pm in the laboratory office with TP1, the findings were confirmed.</p>
<p>D6029</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(11)</p> <p>The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results.</p> <p>This STANDARD is not met as evidenced by: Based on laboratory policy and procedure manual, personnel files, and staff interview, the laboratory director (LD) {serving as the technical supervisor (TS)} failed to ensure that prior to testing patient specimens that all testing personnel receive the proper education and training for the complexity of testing performed in the laboratory. Findings included: 1. Review of the laboratory policy and procedure manual reveals a lack of written policy and procedure for the initial assessment of employee competency. 2. Review of personnel files for 6 out of 6 TP reveals no documentation of initial competency assessment. 3. In an interview on 11/27/2024 at 1:15 pm in the laboratory office with TP1, the findings were confirmed.</p>
<p>D6127</p>	<p>TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(9)</p> <p>The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least semiannually during the first year the individual tests patient specimens.</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory policy and procedure manual, personnel files and staff interview, the LD (serving as the TS) failed to ensure that at least semiannual competency assessment during the first year TP test patient specimens. Findings included: 1. Review of the laboratory policy and procedure manual reveals a lack of written policy and procedure for the at least semiannual assessment of employee competency during the first year of testing patient specimens. 2. Review of personnel files for 6 out of 6 TP reveals no documentation of semiannual competency assessment during the first year of patient testing. 3. In an interview on 11/27/2024 at 1:15 pm in the laboratory office with TP1, the findings were confirmed.</p>