

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 42D0726779	(X3) Date Survey Completed 06/20/2018
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
D2016	<p>SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c)</p> <p>(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.</p> <p>This CONDITION is not met as evidenced by: During an onsite recertification survey on 6/20/2018, based on review of graded reports from American Acadamey of Family Physicians (AAFP) and testing personnel interview, the laboratory failed to successfully participate in proficiency testing for bacteriology for two consecutive proficiency testing events (2017-A and 2017-B). See D2028.</p>
D2020	<p>BACTERIOLOGY CFR(s): 493.823(a)</p>

	<p>Failure to attain an overall testing event score of at least 80 percent is unsatisfactory performance.</p> <p>This STANDARD is not met as evidenced by: During an onsite recertification survey on 6/20/2018, based on review of graded reports from AAFP and interviews with testing personnel and laboratory director, the laboratory failed to attain an overall testing event score of at least 80% in proficiency testing for bacteriology for one of four testing events reviewed (2017-C). Findings include: 1. Review of graded test results from AAFP revealed an overall testing event score of 38% for bacteriology for event 2017-C. 2. The scores were confirmed by testing personnel and laboratory director during the exit conference at 12:45 pm.</p>
D2028	<p>BACTERIOLOGY CFR(s): 493.823(e)</p> <p>Failure to achieve an overall testing event score of satisfactory performance for two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.</p> <p>This STANDARD is not met as evidenced by: During an onsite recertification survey on 6/20/2018, based on review of graded reports from AAFP and interviews with testing personnel and laboratory director, the laboratory failed to achieve satisfactory performance in proficiency testing for the subspecialty bacteriology for two consecutive proficiency testing events reviewed (2017-A and 2017-B). Findings include: 1. Review of graded proficiency testing reports revealed the following scores: a. 2017-A: 60% for presumptive identification b. 2017-B: 60% for presumptive identification 2. Testing personnel and the laboratory director confirmed during the exit interview at 12:45 pm that the laboratory failed to achieve satisfactory proficiency performance.</p>
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: During an onsite recertification survey on 6/20/2018, based on testing personnel record review and testing personnel interview, the laboratory failed to assess the competency of one of one testing personnel for 2016 to 2018. Findings include: 1. One new laboratory testing personnel (DM) was hired in October 2016. 2. Review of testing personnel's file revealed that an initial assessment, a semi-annual assessment, or an annual assessment had not been performed. 3. It was confirmed during the exit interview at 12:45 pm that the initial, semi-annual, or annual competency assessments had not been performed.</p>
D5211	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a)</p>

The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part.

This STANDARD is not met as evidenced by:

During an onsite recertification survey on 6/20/2018, based on proficiency testing record review, and interviews with testing personnel and laboratory director, the laboratory failed to evaluate proficiency testing results for three of four proficiency testing events reviewed from 2017 through 2018 (2017-A, B, and C). Findings include: 1. Review of proficiency testing results revealed the following scores: a. 2017-A: 60% for presumptive identification b. 2017-B: 60% for presumptive identification c. 2017-C: 38% overall event score, 0% for susceptibility testing, 75% for urine sediment There was no documentation of evaluation or corrective action for the failures. 2. Testing personnel and laboratory director confirmed during the exit interview at 12:45 pm that the laboratory had failed to evaluate the unacceptable proficiency testing results.