Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	49D2004750	04/26/2022
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 unannounced CLIA off-site proficiency testing desk review of Blue Ridge Internal Medicine was conducted on 04/26/22 by a Medical Facilities Inspector of the Virginia Department of Health's Office of Licensure and Certification. The laboratory was surveyed under 42 CFR part 493 CLIA Regulations. The laboratory was not in compliance with the following Conditions under 42 CFR part 493 CLIA Regulations: D2016 - 42 C.F.R. 493.803 (a)(b)(c) Condition- Successful Participation.
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 the review of the American Association of Bioanalysts (AAB) proficiency testing (PT) scores for the second event in 2021 and the first event in 2022, the

	CASPER 0155D Individual Laboratory Profile report and an interview, the laboratory failed to achieved satisfactory performance of at least 80% for two out of three events for the Red Blood Cell count (RBC) and hematocrit (HCT) analytes, resulting in unsuccessful performance (Refer to D2130). Event Specialty/Analyte Score: 2021 AAB Non-chemistry Event 2 RBC 0%, Hct 0% 2022 AAB Non-chemistry Event 1 RBC 40%, Hct 60%
D2130	HEMATOLOGY CFR(s): 493.851(f) Failure to achieve satisfactory performance for the same analyte in two consecutive events or two out of three consecutive testing events is unsuccessful performance. This STANDARD is not met as evidenced by: Based on the review of the proficiency testing (PT) scores for the second event in 2021 and the first event in 2022, the CASPER 0155D Individual Laboratory Profile report and an interview, the laboratory failed to achieved satisfactory performance of at least 80% for two out of three events for the Red Blood Cell count (RBC) and hematocrit (HCT) analytes, resulting in unsuccessful performance. Findings include: 1. Off-site PT desk review of the American Association of Bioanalysts (AAB) and the CASPER 0155D Individual Laboratory Profile report revealed the following: Event Specialty/Analyte Score: 2021 AAB Non-chemistry Event 2 RBC 0%, Hct 0% 2022 AAB Non-chemistry Event 1 RBC 40%, Hct 60% The laboratory received unsuccessful AAB PT scores for the above listed analytes. 2. A phone interview with the lab consultant on 04/26/22 at 1345 confirmed the findings.