Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	49D2004750	01/27/2021
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 Initial on-site survey was conducted at the Blue Ridge Internal Medicine on January 27, 2021 by the Virginia Department of Health's Office of Licensure and Certification. The laboratory was surveyed under 42 CFR part 493 CLIA Requirements. The initial contact and entrance interview with laboratory conducted on January 11, 2021 with off-site record review of documentation and a follow-up phone conference on January 22, 2021. Specific deficiencies cited are as follows: The laboratory was not in compliance with the following 42 CFR part 493 CLIA Regulations: D2016 - 42 C.F.R. 493-803 Condition: Successful Participation. The laboratory is performing COVID-19 testing and is in compliance with the applicable COVID-19 reporting requirements.
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: A. Based on the review of the proficiency testing (PT) scores for all three events in 2020, the review of the CASPER 0155D Individual PT report and an interview with the primary testing personnel, the laboratory failed to achieved satisfactory performance of at least 80% for two consecutive events for the following parameters, resulting in unsuccessful performance (Cross Reference D 2096): 2020 Alanine aminotransferase (ALT) Event 1= 60% Event 2=0% Sodium (NA) Event 2= 0% Event 3= 0% B. Based on the review of the proficiency testing (PT) scores for all three events in 2020, the review of the CASPER 0155D Individual PT report, lack of documentation and an interview with the lab consultant and primary testing personnel, the laboratory failed to submit the PT test results for the Chemistry and Hematology modules within the specified time frame for one (1) of 3 events in 2020. (Cross Reference D2093 and D2127).
D2093	ROUTINE CHEMISTRY CFR(s): 493.841(d) Failure to return proficiency testing results to the proficiency testing program within the time frame specified by the program is unsatisfactory performance and results in a score of 0 for the testing event. This STANDARD is not met as evidenced by: Based on the review of the proficiency testing (PT) scores for all three events in 2020, the review of the CASPER 0155D Individual PT report, lack of documentation and an interview with the primary testing personnel, the laboratory failed to submit the PT results for the Chemistry module within the specified time frame for one (1) of 3 events in 2020. Findings include: 1. Review of the American Association of Bioanalysts (AAB) PT scores for the all three events in 2020 revealed a score of 0% and lack of documentation of submission of test results for the Chemistry module second event analytes: Alamine aminotrasferease, albumin, alkaline phosphatase, bicarbonate, bilirubin total, calcium, chloride, cholesterol total, creatinine, glucose, potassium, sodium, protein total, triglycerides, urea nitrogen, uric acid, amylase, creatin kinase total, HDL cholesterol, iron, lipase, thyroid stimulating hormone, thyroxine Free, vitamin D, ferritin, folate, prostate specific Ag, testosterone, triiodothyronine free, and vitamin B12. 2. An interview with the lab consultant and primary testing personnel on January 27, 2021 at approximately 10:00 AM confirmed that there was no documentation of submitted test results for the chemistry module for the second event in 2020. They stated, "Due to the confusion of shipments with COVID, our PT samples were received downstairs. When we realized the PT shipment was downstairs, it was too late to submit results to AAB. We did run the samples and did a self-grade."
D2096	ROUTINE CHEMISTRY CFR(s): 493.841(f) Failure to achieve satisfactory performance for the same analyte or test in two consecutive testing 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 all three events in 2020, the review of the CASPER 0155D Individual PT report and an interview with the primary testing personnel, the laboratory failed to achieved satisfactory performance of at least 80% for two consecutive events for the alanine aminotransferase (ALT) and Sodium (NA) parameters, resulting in unsuccessful performance. Findings include: 1. Review of the American Association of Bioanalysts (AAB) PT scores for all three events in the calendar year 2020 revealed the following: ALT- Event 1= 60%; Event 2=0% NA- Event 2= 0%; Event 3= 0% The laboratory received an unsuccessful AAB PT score for the above listed analytes. 2. An interview with the lab consultant and primary testing personnel on January 27, 2021 at approximately 9:45 AM confirmed the findings.
D2127	HEMATOLOGY CFR(s): 493.851(d) Failure to return proficiency testing results to the proficiency testing program within the time frame specified by the program is unsatisfactory performance and results in a score of 0 for the testing event. This STANDARD is not met as evidenced by: Based on the review of the proficiency testing (PT) scores for all three events in 2020, the review of the CASPER 0155D Individual PT report, lack of documentation and an interview with the primary testing personnel, the laboratory failed to submit the PT results for the hematology module within the specified time frame for one (1) of 3 events in 2020. Findings include: 1. Review of the American Association of Bioanalysts (AAB) PT scores for the all three events in 2020 revealed a score of 0% and lack of documentation of submission of test results for the Hematology module second event analytes: Cell Identification, Red Blood Cell, White Blood Cell Platelets, Hemoglobin and Hematocrit. 2. An interview with the lab consultant and primary testing personnel on January 27, 2021 at approximately 10:00 AM confirmed that there was no documentation of submitted test results for the Hematology module for the second event in 2020. They stated, "Due to the confusion of shipments with COVID, our PT samples were received downstairs. When we realized the PT shipment was downstairs, it was too late to submit results to AAB. We did run the samples and did a self-grade."