

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 34D0947561	(X3) Date Survey Completed 06/18/2021
Name of Provider or Supplier Blue Ridge Medical Group, Inc DbA	Street Address, City, State 5920 Us Highway 70 East, Nebo, NC	
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
D3031	<p>RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3)</p> <p>Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years.</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory's procedures, review of 2019, 2020, and 2021 analyzer service, maintenance, and calibration records, and interview with the lab supervisor 6/18/21, the laboratory failed to retain all calibration documentation for the Beckman Coulter Act Diff 2 hematology analyzer. Findings: Review of the Act Diff Calibration procedure states, "Important after you have finished calibration, be sure that you have the following printouts for your records: - Reproducibility Summary results - Carryover summary results - Current CAL factors(prior to calibration) - Calibration Summary results - New CAL factors(after calibration)" Review of the 2019, 2020, and 2020 analyzer service, maintenance, and calibration records revealed: 1. Clinical engineering performed service on 2/4/19. The service record stated, "...Repro and carry-over passed. Completed S-cal; all parameters passed with no adjustments needed. Gave reports to....." The Act Diff 2 maintenance log was initialed as calibration performed on 2/4/19. The calibration records revealed no documentation for the 2/4/19 calibration. 2. Clinical engineering performed service on 4/29/19. The service record stated, "Pre-calibration procedure and S-cal completed..." The Act Diff 2 maintenance log was initialed as calibration performed on 4/29/19. The calibration records revealed only the carryover and reproducibility summaries. There was no other documentation available for the 4/29/19 calibration. During interview at approximately 12:45pm, the laboratory supervisor confirmed the calibration records were not available.</p>