Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	34D0699936	06/17/2021
Name of Provider or Supplier	**Street Address, City, State**	
Blue Ridge Medical Group, Inc Dba	2293 Sugar Hill Road, Ste D,, Marion, 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
D5477	CONTROL PROCEDURES CFR(s): 493.1256(e)(4)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e)(4) Before, or concurrent with the initial use-- (e)(4)(i) Check each batch of media for sterility if sterility is required for testing; (e)(4)(ii) Check each batch of media for its ability to support growth and, as appropriate, select or inhibit specific organisms or produce a biochemical response; and (e)(4)(iii) Document the physical characteristics of the media when compromised and report any deterioration in the media to the manufacturer. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of manufacturer's instructions, review of laboratory records, and interview with TP(testing personnel) 6/17/21, the laboratory failed to perform and document media sterility checks as required. Findings: Review of the BD(Becton Dickinson) BBL Group A Selective Strep Agar with 5% Sheep Blood instructions with revision date April 2015 located in the laboratory's procedure manual states under III. Additional Quality Control, "5. Incubate uninoculated representative plates at 35 +/- 2 degrees C(Celsius) for 72 h(hours) and examine for microbial contamination." Review of 2019, 2020, and 2021 laboratory records revealed the laboratory had documented positive and negative quality control for each lot number or shipment of media and had documented the physical characteristics of the media. The laboratory had not performed or documented sterility checks as required. Review of laboratory records revealed approximately 963 patients were tested during the time period reviewed in 2019, 2020, and 2021. During interview at approximately 2:15pm, TP#1 confirmed they had not checked each lot number or shipment of the Group A Selective Strep Agar for sterility. She stated they were unaware sterility checks had to be performed.
D6072	TESTING PERSONNEL RESPONSIBILITIES

	CFR(s): 493.1425(b)(3) Each individual performing moderate complexity testing must adhere to the laboratory's quality control policies, document all quality control activities, instrument and procedural calibrations and maintenance performed. This STANDARD is not met as evidenced by: Based on review of laboratory's procedures, and review of 2019, 2020, and 2021 analyzer service and calibration records 6/17/21, the TP (testing personnel) failed to follow the laboratory procedure to perform calibration on the Beckman Coulter Act Diff 2 hematology analyzer as required. Findings: The laboratory's AcT Diff 2 calibration procedure states, "Calibration of the Coulter AcT Diff 2 should be verified every 6 months or following the replacement of any major instrument component that could affect the accuracy of the instrument." Review of 2019, 2020, and 2021 analyzer and calibration service records for the Beckman Coulter Act Diff 2 hematology analyzer revealed: 1. Clinical engineering replaced the Hgb(hemoglobin) lamp during a service visit on 6/25/19. The TP failed to calibrate the Act Diff 2 analyzer until 1/30/20, a period of 7 months after the service and after the last calibration that was performed on 6/13/19, prior to the service. 2. Clinical engineering replaced the WBC(White Blood Cell) bath and the Hgb lamp on 8/25/20. The TP failed to calibrate the Act Diff 2 analyzer until 10/22/20, a period of 2 months after the service.