Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	44D1060262	06/20/2022
Name of Provider or Supplier	**Street Address, City, State**	
Raleigh Group Pc	3161 Highway 64, Suite #100, Eads, TN	

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
D2123	HEMATOLOGY CFR(s): 493.851(c) Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if-- (1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results; (2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and (3) The laboratory participated in the previous two proficiency testing events. This STANDARD is not met as evidenced by: Based on observation of the laboratory, review of the Centers for Medicare and Medicaid Services Casper Report 155 (CMS 155), the laboratory's proficiency testing (PT) records, and interview with the technical consultant, the laboratory failed to participate in proficiency testing for complete blood count (CBC) for 2022 event one. The findings include: 1. Observation of the laboratory on 06/20/22 at 8:00 am revealed the Beckman Coulter AcT Diff CBC instrument on the counter in use for patient testing (system ID 503003). 2. Review of the form CMS 155 revealed no proficiency testing scores for 2022 event one. 3. Review of the laboratory's PT records revealed a lack of proficiency testing records for 2022 event one. 3. Interview with the technical consultant on 06/20/22 at 1 pm confirmed the laboratory failed to participate in proficiency testing for 2022 event one for CBC but was performing patient CBC testing during the period.
D5459	CONTROL PROCEDURES CFR(s): 493.1256(d)(5)(g)

	Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- Each electrophoretic procedure include, concurrent with patient specimens, at least one control material containing the substances being identified or measured. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on observation of the laboratory, review of the laboratory's quality control records, review of an email communication and interview with the technical consultant, the laboratory failed to verify the correct instrument was selected when entering quality control (QC) ranges in the complete blood count (CBC) instrument, resulting in the use of incorrect QC ranges from 05/04/20 to 06/20/22 with approximately 2,300 patients tested during the affected period. All lots used during the period were affected. The findings include: 1. Observation of the laboratory on 06 /20/22 at 8 am revealed the Beckman Coulter AcT Diff CBC instrument on the counter in use for patient testing (system ID number 503003). 2. Review of the laboratory's CBC quality control records, including cumulative reports and manufacturer assay sheets, from 05/04/20 to the date of the survey on 06/20/22, revealed the laboratory used the stated QC ranges for the Beckman Coulter AcT Diff 2 instead of the Beckman Coulter AcT Diff instrument. The laboratory did not verify the correct instrument QC ranges were used. All lots used during the period were affected. 3. Review of an email received from the laboratory on 06/23/22 revealed approximately 2,300 patients were tested during the period the incorrect QC ranges were in use. 4. Interview with the technical consultant on 06/20/22 at 1 pm confirmed the laboratory uses the manufacturer stated QC ranges and failed to verify the correct instrument was used when entering control ranges in the instrument, resulting in the use of incorrect quality control ranges from 05/04/20 to 06/20/22 with all lot numbers used during the period affected.