Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	44D1060262	01/24/2024
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
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: Based on observation of the laboratory, patient test record review, procedure manual review, and staff interviews, the laboratory failed to ensure the laboratory director approved the procedure manual for the Beckman Coulter DxH 500 complete blood count (CBC) instrument prior to patient testing which began on 05/30/2023. The findings include: 1. Observation of the laboratory on 01/24/2024 at 9:30 am revealed the Beckman Coulter DxH 500 CBC instrument (serial 83196896) in use for patient testing. 2. Review of patient test records revealed the first patient (patient #99384) reported on 05/30/2023. 3. Review of the operator's procedure manual "Instructions for Use" for the Beckman Coulter DxH 500 CBC instrument revealed the laboratory director had not approved the procedure. 4. Interview with the technical consultant and testing person one on 01/24/2024 at 12:30 pm, confirmed the Instructions for Use manual was used as the laboratory procedure for performance of CBC testing on the Beckman Coulter DxH and it had not been approved by the laboratory director.