Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	44D0315051	01/05/2023
Name of Provider or Supplier	**Street Address, City, State**	
Raleigh Group, Pc	2860 Covington Pike, Memphis, 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
D2005	ENROLLMENT CFR(s): 493.801(a)(4) Authorize the proficiency testing program to release to HHS all data required to-- (i) Determine the laboratory's compliance with this subpart; and (ii) Make PT results available to the public as required in section 353(f)(3)(F) of the Public Health Service Act. 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 the laboratory's PT program catalog, and interview with the technical consultant, the laboratory enrolled in the incorrect PT program for total (neonatal) bilirubin for 2022 and 2023, resulting in the laboratory failing to ensure the Centers for Medicare and Medicaid Services (CMS) was notified of the laboratory's PT results for total bilirubin in 2022 and 2023. The findings include: 1. Observation of the laboratory on 01/05/23 at 8:45 am revealed the Reichert Unistat Bilirubinometer in use for performing total bilirubin testing on neonates. 2. Review of the laboratory's CMS 155 revealed no bilirubin results were reported to CMS in 2022. 3. Review of the laboratory's proficiency testing enrollment records and the American Proficiency Institute (API) website revealed the following: Enrollment for 2022 and 2023 was in program #129-Neonatal Bilirubin-2 Samples The 2022 and 2023 catalog for API stated that "Catalog #129 is not scored for CMS" 4. Interview with the technical consultant on 01/05/23 at 12:30 pm confirmed the laboratory enrolled in the incorrect proficiency program for the total bilirubin analyte resulting in the laboratory failing to ensure the results were reported to CMS.
D3000	FACILITY ADMINISTRATION CFR(s): 493.1100

	Each laboratory that performs nonwaived testing must meet the applicable requirements under 493.1101 through 493.1105, unless HHS approves a procedure that provides equivalent quality testing as specified in Appendix C of the State Operations Manual (CMS Pub. 7). (a) Reporting of SARS-CoV-2 test results During the Public Health Emergency, as defined in 400.200 of this chapter, each laboratory that performs a test that is intended to detect SARS-CoV-2 or to diagnose a possible case of COVID-19 (hereinafter referred to as a "SARS-CoV-2 test") must report SARS-CoV-2 test results to the Secretary in such form and manner, and at such timing and frequency, as the Secretary may prescribe. This CONDITION is not met as evidenced by: Based on observation of the laboratory, review of patient SARS-CoV-2 test records and interview with the technical consultant, the laboratory failed to report positive SARS-CoV-2 test results as required for one of four days selected for review from 2021 and 2022. The findings include: 1. Observation of the laboratory on 01/05/23 at 9:00 am revealed patient testing being performed for SARS-COV-2 antigen on the BD Veritor waived test system. 2. SARS-CoV-2 patient logs and test reporting documentation was reviewed for the dates of 03/11/21, 09/22/21, 02/01/22 and 12/03 /22. 3. Documentation revealed that positive SARS-CoV results were not reported as required on 03/11/21 for one patient (#96447). 4. Interview with the technical consultant on 01/05/23 at 4:30 pm confirmed the laboratory was unable to provide documentation that positive SARS-CoV-2 results were reported as required for one of four dates selected from 2021 and 2022.
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) 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. This STANDARD is not met as evidenced by: Based on review of the laboratory's quality control (QC) records for bilirubin and interview with the technical consultant, the laboratory failed to retain complete analytic QC records for the bilirubin analyte that include the time the QC was performed in 2021, 2022, and 2023. The findings include: 1. Review of the laboratory's QC records for bilirubin revealed no record of the time the QC was performed for five of five selected dates (03/03/21, 06/03/21, 12/13/21, 06/04/22, 12 /29/22). 2. Interview with the technical consultant on 01/05/23 at 4:30 pm confirmed the laboratory failed to retain QC analytic records that included the time the QC was performed for five of five dates selected in 2021 and 2022. She further confirmed the laboratory's forms did not include the time bilirubin QC was performed for the last two years through the date of the survey on 01/05/23.
D6046	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8) (b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently.

	This STANDARD is not met as evidenced by: Based on review of testing personnel competency assessment records, personnel records and interview with the technical consultant, competency assessment for testing person #4 was not performed by the technical consultant in 2021. The findings include: 1. Review of testing personnel competency assessment records revealed that competency assessments were performed by testing person #1 as follows: Testing person #3 on 07/05/21 for Complete Blood Count and Bilirubin. Testing person #4 on 01/20/21 and 07/01/21 for Complete Blood Count and Bilirubin. 2. Review of personnel records for testing person #1 revealed no delegation of duties for performing technical consultant duties and education that did not meet the regulatory requirements of a technical consultant. 3. Interview with the technical consultant on 01/05/23 at 11 am confirmed testing personnel competencies were performed by testing person #1 for testing person #3 and #4 in 2021. She further confirmed that testing person #1 does not have the appropriate regulatory education for performing the duties of the technical consultant. The technical consultant failed to perform competency assessment for testing person #3 on 07/05/21 and #4 on 01/20/21 and 07/01/21.