Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	44D0315051	02/06/2020
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
D6004	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(a)(b) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (a) The laboratory director, if qualified, may perform the duties of the technical consultant, clinical consultant, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications of 493.1409, 493.1415, and 493.1421, respectively. (b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed. This STANDARD is not met as evidenced by: Based on review of the Aspen Web system, patient test reports, Clinical Laboratory Improvement Amendments of 1988 (CLIA) regulations, and interview with the laboratory liaison, the laboratory director failed to ensure compliance with the CLIA regulations in 2019. The findings include: 1) Review of the Aspen Web system revealed the laboratory's previous CLIA certificate expired on February 22, 2019 due to nonpayment of fees and was reactivated as a certificate of registration on October 15, 2019. 2) Review of patient test reports revealed the laboratory continued patient testing from February 23, 2019 to October 14, 2019 when the laboratory did not possess a current CLIA certificate. 3) Review of CLIA regulation at 493.1 revealed the following: "This part sets forth the conditions that all laboratories must meet to be certified to perform testing on human specimens under the Clinical Laboratory Improvement Amendments of 1988 (CLIA)." 4) Review of CLIA regulations at 493.3 revealed the following: "Applicability: (a) Basic rule. Except as specified in paragraph (b) of this section, a laboratory will be cited as out of compliance with section 353 of the Public Health Service Act unless it--(1) Has a current, unrevoked or unsuspended certificate of waiver, a registration certificate, certificate of compliance, certificate for

	PPM procedures, or certificate of accreditation issued by HHS applicable to the category of examinations or procedures performed by the laboratory;" 5) Interview with the laboratory liaison on February 6, 2020 at 1:15 p.m. confirmed the laboratory director failed to ensure compliance with the CLIA regulations in 2019 when the laboratory continued to test patients without a valid CLIA certificate.