Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	44D0315051	12/05/2018
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
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: Based on observation of the laboratory and interview with the lead testing personnel, the laboratory failed to label saline reagent with expiration date in 2018. The findings include: 1. Observation of the laboratory on December 5, 2018 at 9:30 am revealed a bottle labeled "Saline" in use for patient testing for wet prep. There was no expiration date on the vial. 2. Interview with the lead testing personnel on December 5, 2018 at 4:00 pm confirmed the laboratory failed to ensure reagents were labeled with expiration date when it did not label the saline reagent with expiration date in 2018.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on observation of the laboratory, review of the complete blood count (CBC) control package insert, the laboratory's quality control data, and interview with the lead testing personnel, the laboratory failed to ensure complete blood count (CBC)

	controls were not used past their expiration date in 2018. The findings include: 1. Observation of the laboratory on December 5, 2018 at 9:30 am revealed CBC controls in use labeled with an open date of 11-02-2018 and no corrected expiration date (lot #s 068200, 078200, 088200). 2. Review of the CBC control package insert revealed the following: 35 day open vial stability if the maximum number of times performed is 20 times within 35 days. 3. Review of the laboratory's quality control data revealed that the quality controls had been used past the maximum allowable number of 20 times for all three lot numbers. 4. Interview with the lead testing personnel on December 5, 2018 at 4:00 pm confirmed that control lot numbers 068200, 078200, and 088200 were used past the maximum number of allowed runs in 2018. The laboratory failed to ensure the CBC controls were not used past their expiration date in 2018.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: Based on observation of the laboratory, review of the Reichert Unistat Bilirubinometer user guide, the laboratory's calibration and calibration verifcation records for the Unistat Bilirubinometer, and interview with the lead testing personnel, the laboratory failed to verify the low measuring range of the Unistat bilirubinometer in 2017 and 2018 with patient testing performed. The findings include: 1. Observation of the laboratory on December 5, 2018 at 9:30 am revealed the Unistat Bilirubinometer in use for patient testing. 2. Review of the Reichert Unistat Bilirubinometer user guide revealed the following: The instrument has a measuring range of 0-40 mg/dL. Calibration verification may be performed using manufacturer's glass cuvettes that cover the mid and high range. A sample cuvette filled with distilled water may be used to check zero. 3. Review of the 2017 and 2018 calibration and calibration verification records for the Reichert Unistat Biliruminometer revealed there was no check of the lower measuring range of zero. 4. Interview with the

	technical consultant on December 5, 2018 at 4:00 pm confirmed the laboratory failed to verify the lower measuring range of the Unistat Bilirubinometer when it did not use distilled water to check zero in 2017 and 2018.
D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: Based on review of patient test reports for bilirubin, patient test reports for red blood cell count and interview with the technical consultant, the final patient test report failed to include units of measure for the bilirubin and red blood cell count in 2017 and 2018. The findings include: 1. Review of the final patient test reports for patient numbers 2,4,6,8,10, and 11 revealed patient testing reported for bilirubin in 2017 and 2018 with no unit of measure. 2. Review of final patient test reports and instrument printouts for patient numbers 1, 3, 5, 7, and 9 revealed patient testing reported for red blood cell count in 2017 and 2018 with incorrect units of measure on the patient reports. Unit of measure used = X10^3/uL, correct unit of measure from instrument printout = X10^6/uL. 3. Interview with the technical consultant on December 5, 2018 at 4:00 pm confirmed there were no units of measure included on the final patient reports for bilirubin and incorrect units of meaure for the red blood cell count in 2017 and 2018.