Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 19D0648840	(X3) Date Survey Completed 02/26/2018
Name of Provider or Supplier Rheumatology Group, Llc, The	**Street Address, City, State** 2633 Napoleon Ave Suite 530, New Orleans, LA	

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
D0000	A Certification Survey was conducted on February 26, 2018 at The Rheumatology Group, LLC-CLIA ID # 19D0648840. The laboratory was found in compliance with 42 CFR 493 Requirement for Laboratories; however, standard deficiencies were cited.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the laboratory failed to ensure written policies and procedures to assess competency for the Technical Consultant and General Supervisor were complete. Findings: 1. Review of the laboratory's CMS-209 form (Laboratory Personnel Report) revealed Personnel 2 serves as the Technical Consultant and General Supervisor. 2. Review of the laboratory's policies and procedures revealed the laboratory did not have a policy for competency assessment of Technical Consultant and General Supervisor. 3. Review of personnel records revealed competency assessments for the duties of Technical Consultant and General Supervisor were not performed. 4. In interview on February 26, 2018 at 9:59 am, Personnel 2 stated competency assessments for her duties as Technical Consultant and General Supervisor were not performed.
D5221	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d) All proficiency testing evaluation and verification activities must be documented.

	This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the laboratory failed to maintain documentation of the assessment for unacceptable proficiency testing (PT) results. Findings: 1. Review of the laboratory's 2017 College of American Pathologists (CAP) Hematology Auto Differentials PT results revealed the laboratory received the following unacceptable result: 2017 1st Event Cell ID/Flow Differential-80% 2. Review of the laboratory's policies and procedures revealed the laboratory utilizes an "Investigative Report" form for unacceptable PT results. 3. Further review of the laboratory's 2017 PT records revealed an "Investigative Report" for the identified unacceptable PT event was not found. 4. In interview on February 26, 2018 at 11:56 am, Personnel 2 stated she did not complete an "Investigative Report" form for the identified unacceptable PT event.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on observation, record review, and interview with personnel, the laboratory failed to monitor the temperature of areas where laboratory supplies are stored per manufacturer requirements. Findings: 1. Observation by surveyor during laboratory tour on February 26, 2018 revealed the laboratory did not monitor the temperature for the following areas: Blood Draw Room and Storage Area 2. Review of the manufacturer requirements listed on the packaging of the BD Vacutainer and Greiner-one VACUETTE blood collection tubes revealed a temperature requirement of 4-25 degrees Celsius. 3. Further observation during laboratory tour revealed the following items stored without temperature monitors: a) Storage Area: BD Vacutainer K2EDTA Blood Collection Tubes, Lot # 7219631, Quantity: two (2) packs BD Vacutainer K2EDTA Blood Collection Tubes, Lot # 7279892, Quantity: four (4) packs VACUETTE Serum Separator Clot Activator Blood Collection Tubes, Lot # B171039H, Quantity: three (3) packs b) Blood Draw Room: VACUETTE Serum Separator Clot Activator Blood Collection Tubes, Lot # B171039H, Quantity: one (1) pack and approximately 15 (fifteen tubes) BD Vacutainer K2EDTA Blood Collection Tubes, Lot # 7219631, Quantity: approximately fifteen (15) tubes 4. In interview on February 26, 2018 at 9:25 am, Personnel 2 stated the laboratory does not monitor the temperature of the blood draw room or storage area. Personnel 2 stated she was not aware blood collection tubes had a temperature requirement.
D6014	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(iii) 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. (e) The laboratory

	director must-- (e)(3) Ensure that-- (e)(3)(iii) Laboratory personnel are performing the test methods as required for accurate and reliable results. This STANDARD is not met as evidenced by: Based on observation, record review, and interview with personnel, the Laboratory Director failed to ensure laboratory personnel performed testing as required. Refer to D5413.
D6019	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iv) 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. (e) The laboratory director must-- (e)(4)(iv) Ensure that an approved corrective action plan is followed when any proficiency testing results are found to be unacceptable or unsatisfactory. This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Laboratory Director failed to ensure the laboratory followed the corrective action plan for unacceptable proficiency testing results. Refer to D5221.
D6030	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(12) 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. (e) The laboratory director must-- (e)(12) Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills; This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Laboratory Director failed to ensure policies and procedures were established for assessing personnel competency, and whenever necessary, identify needs for remedial training or continuing education to improve skills. Findings: 1. Review of the laboratory's CMS-209 form (Laboratory Personnel Report) revealed Personnel 2 serves as the Technical Consultant and Testing Personnel. 2. Review of personnel records revealed the laboratory utilizes the following forms: a) "Laboratory Personnel Evaluation" form which includes assessment of Laboratory Skills and Work Ethic b) "Laboratory Competency Assessment" form which includes: direct observation of test performance, monitoring the recording/reporting of test results, review of test records, direct observation of instrument maintenance/function checks, Proficiency testing /blind testing, and evaluation of problem solving skills 3. Review of competency

	records for Personnel 2 revealed the Laboratory Director completed the "Laboratory Personnel Evaluation" form for Personnel 2 on May 8, 2017; however, the form was not test specific. 4. Further review of Personal 2's competency records revealed assessments for testing were performed; however, not by the Laboratory Director. 5. In interview on February 26, 2018 at 9:59 am, Personnel 2 stated her competency assessments were performed by Personnel 3. 6. The laboratory failed to ensure written policies and procedures to assess competency for the Technical Consultant were complete. Refer to D5209.
D6087	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(3)(iii) The laboratory director must ensure that laboratory personnel are performing the test methods as required for accurate and reliable results. This STANDARD is not met as evidenced by: Based on observation, record review and interview with personnel, the Laboratory Director failed to ensure laboratory personnel performed test methods as required. Refer to D5413.
D6103	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(13) The laboratory director must ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills. This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Laboratory Director failed to ensure policies and procedures were established for assessing personnel competency, and whenever necessary, identify needs for remedial training or continuing education to improve skills. Findings: 1. In interview on February 26, 2018 at 9:59 am, Personnel 2 stated she is the only personnel performing high complexity testing. 2. Review of the laboratory's CMS-209 form (Laboratory Personnel Report) revealed the Laboratory Director also serves as the Technical Supervisor. 2. Review of personnel records revealed the laboratory utilizes the following forms: a) "Laboratory Personnel Evaluation" form which includes assessment of Laboratory Skills and Work Ethic b) "Laboratory Competency Assessment" form which includes: direct observation of test performance, monitoring the recording/reporting of test results, review of test records, direct observation of instrument maintenance/function checks, Proficiency testing/blind testing, and evaluation of problem solving skills 3. Review of competency records for Personnel 2 revealed the Laboratory Director completed the "Laboratory Personnel Evaluation" form for Personnel 2 on May 8, 2017; however, the form was not test specific. 4. In interview on February 26, 2018 at 12:30 pm, Personnel 2 stated the Laboratory Director does not perform her competency assessment for high complexity testing. 5. In further interview at 12:30 pm, Personnel 3 stated she checks to make sure proficiency testing for high complexity tests have been performed by Personnel 2. Personnel 3 further stated since

	she does not perform the high complexity testing she does not perform any further assessments for Personnel 2. 6. The laboratory failed to ensure written policies and procedures to assess competency for General Supervisor were complete. Refer to D5209.