Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	14D0892372	09/04/2019
Name of Provider or Supplier	**Street Address, City, State**	
Rheumatic Disease Center Physicians Sc	150 N River Rd, Des Plaines, IL	

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
D2076	GENERAL IMMUNOLOGY CFR(s): 493.837(b) Failure to attain an overall testing event score of at least 80 percent is unsatisfactory performance. This STANDARD is not met as evidenced by: Based on a review of American Proficiency Institute (API) proficiency testing (PT) records and an interview with the technical consultant (TC), the laboratory failed to attain an overall testing event score of at least 80 percent for testing in the subspecialty of General Immunology, during the year of 2019. Findings: 1. The API Immunology results for 2018 and 2019 were reviewed. 2. The laboratory failed to receive a satisfactory performance score for General Immunology testing. The API-PT records revealed the following: *For event #1 of 2019, the laboratory receive an overall score of 73% in General Immunology. *The analyte Immunoprotein Complement C3 (C3) received a score of 20%; and *Rheumatoid Factor (RF) PT results received a "not graded" result due to less than 10 participants. 3. On a recertification survey conducted 09/04/2019 at 3:15 PM, the TC confirmed the above findings.
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, the Laboratory Personnel Report (CMS 209), and an

	interview with the technical consultant (TC1); the laboratory failed to establish written procedures to assess employees performing TC and technical supervisor (TS) responsibilities, affecting 1 out of 1 employee. Findings: 1. The CMS 209, personnel records, and the laboratory's Performance/Competency Testing policies were reviewed. 2. The competency policy failed to establish a written competency procedure that assesses the TC's performance of the following responsibilities: *Providing technical and scientific oversight of the laboratory; *Availability *Selection of test methodology appropriate for the clinical use of the test results; *Verification of the test procedures performed and the establishment of the laboratory's test performance characteristics; *Enrollment and participation in an HHS approved proficiency testing (PT) program commensurate with the services offered; *Establishing a quality control program appropriate for the testing performed and establishing the parameters for acceptable levels of analytic performance and ensuring that these levels are maintained throughout the entire testing process from the initial receipt of the specimen, through sample analysis and reporting of test results; *Resolving technical problems and ensuring that remedial actions are taken whenever test systems deviate from the laboratory's established performance specifications; *Ensuring that patient test results are not reported until all corrective actions have been taken and the test system is functioning properly; *Identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed; and *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. 3. The competency policy failed to include the assessment of the TC and TS. 4. On a recertification survey conducted 09/04/2019 at 3:15 PM, the TC confirmed the above findings.
D5213	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(1) The laboratory must verify the accuracy of any analyte or subspecialty without analytes listed in subpart I of this part that is not evaluated or scored by a CMS-approved proficiency testing program. This STANDARD is not met as evidenced by: Based on record review, the laboratory's American Proficiency Institute (API) proficiency testing (PT) records, manual, and an interview with the technical consultant (TC); the laboratory failed to verify the accuracy of the Rheumatoid Factor (RF) testing not scored by the PT program, during event #1 of 2019 Findings: 1. The API Immunology results for 2018 and 2019 and PT policy and procedures were reviewed. 2. The API-PT records showed that the Rheumatoid Factor (RF) PT results received a "not graded" result due to less than 10 participants. 3. The laboratory's PT policy states the following: *If proficiency testing is unavailable for a limited number of tests, competency/comparison testing (Split sampling) will be performed on these tests. 4. The laboratory failed to follow it's PT policy to send split samples to verify the accuracy of it's RF testing during the period of the 1st event in 2019. 5. On a recertification survey conducted 09/04/2019 at 3:15 PM, the TC confirmed the above findings.
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a)

	Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: Based on direct observation, record review, manufacturer's instructions, and an interview with the technical consultant (TC); the laboratory failed to perform testing as instructed by the manufacturer and in a manner that provide test results within the laboratory's stated performance specifications for Immunoprotein Analysis in the subspecialty of General Immunology testing, affecting all patients tested after 06/19 /2019. Findings: 1. The procedures manual, the manufacturer's liquid controls package insert, the quality control (QC) printouts dated 08/28/2019, and patients' test results from 09/04/2019 were reviewed. 2. On 09/04/2016 at 1:30 PM, during a tour of the laboratory, the surveyor observed the following controls used for testing C-Reactive Protein (CRP), Complement C3 (C3), and Complement C4 (C4): *Level 1 and Level #2 - Lot #L851, expiration date 04/30/2020. 3. The controls package insert for Lot #L851 showed the following ranges for the CRP, C3 and C4: *Level 1 - CRP- 0.7-1.3 mg/dL; C3 - 74-110 mg/dL; & C4 - 13-19 mg/dL *Level 2 - CRP- 3.3-4.3 mg/dL; C3 - 210-256 mg/dL; & C4 - 40-50 mg/dL. 4. The QC printouts revealed that the laboratory failed to input the acceptable ranges of the new control lot (#L851), prior to testing patients. The following QC ranges changed: *Level #1 - C3 acceptable range changed from 76-108 mg/dL to 74-110 mg/dL; *Level #2 - C3 acceptable range changed from 211-255 mg/dL to 210-256 mg/dL; C4 acceptable range changed from 41-49 mg/dL to 40-50 mg/dL; 5. The procedure manual and the manufacturer's instructions require newly assigned Control ranges be manually entered into the analyzer prior to patient testing. 6. The laboratory began using Lot #L851 on 06/19 /2019. 7. On a recertification survey conducted 09/04/2019 at 3:15 PM, the TC confirmed the above findings.
D6033	TECHNICAL CONSULTANT-MODERATE COMPEXITY CFR(s): 493.1409 The laboratory must have a technical consultant who meets the qualification requirements of 493.1411 of this subpart and provides technical oversight in accordance with 493.1413 of this subpart. This CONDITION is not met as evidenced by: Based on records, manual, and an interview with the technical consultant (TC); the TC failed to provide technical oversight in accordance with 493.1413 of this subpart in the subspecialty of General Immunology, Chemistry, and Hematology. Findings Include: 1. The TC failed to enroll and participate in an HHS approved proficiency testing program commensurate with the services offered when API-PT program no longer scored PT results. See D6041. 2. The TC failed to evaluate and document the competency and training of all testing personnel. See D6046.
D6041	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(3) (b) The technical consultant is responsible for-- (b)(3) Enrollment and participation in an HHS approved proficiency testing program commensurate with the services

	offered; This STANDARD is not met as evidenced by: Based on a review of American Proficiency Institute (API) proficiency testing (PT) records, manual and an interview with the technical consultant (TC); the TC failed to enroll and participate in an HHS approved proficiency testing program commensurate with the services offered for testing Rheumatoid Factor (RF), during the year of 2019. Findings: 1. The API Immunology results for 2018 and 2019 and PT policies were reviewed. 2. The laboratory received a "Not Graded" result for RF testing due to less than 10 participants for event #1 of 2019. 3. The TC failed to seek another PT program to enroll for RF testing using the laboratory's current test system. 4. The TC failed to follow the laboratory's PT policy to begin split sample testing when proficiency testing is unavailable.
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 record review, the Laboratory Personnel Report (CMS 209) and an interview with the technical consultant (TC); the TC failed to evaluate the competency of all testing personnel and assure that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently, affecting 3 out of 3 testing personnel (TP). Findings: 1. The CMS 209, personnel records, and the laboratory's Performance/Competency Testing policies were reviewed. 2. The Performance/Competency policy states the following: "Note: The competency should cover all instruments and test kits for which the employee is trained." 3. TP1, TP2, and TP3 were listed on the CMS 209 for performing Cell Blood Count (CBC) analysis, routine Chemistry, and General Immunology tests. 4. The personnel files for TP1, TP2, and TP3 revealed the following: *A signed statement by the laboratory director that states: 'Employee has successfully demonstrated that he/she can function adequately in all areas and is ready to assume duties'. *TP1, TP2, and TP3 were hired between October of 2018 and August of 2019. *The laboratory failed to have training documentation for all the tests performed for TP2 and TP3. *The laboratory failed to identify on the competency documents of TP1, TP2, and TP3, the test system the TP had been assessed. *TP1, TP2, and TP3 were performing patient testing in the laboratory. 5. On a recertification survey conducted 09/04/2019 at 3:15 PM, the TC confirmed the above findings.
D6063	LABORATORY TESTING PERSONNEL CFR(s): 493.1421 The laboratory must have a sufficient number of individuals who meet the qualification requirements of 493.1423, to perform the functions specified in 493. 1425 for the volume and complexity of tests performed. This CONDITION is not met as evidenced by:

	Based on record review, the Laboratory Personnel Report (CMS-209) and an interview with the technical consultant (TC); the laboratory failed to employ individuals who meet the qualification requirements of 493.1423 for testing personnel (TP) for 1 out of 2 TP. Finding: 1. The laboratory failed to ensure laboratory personnel meet the qualification requirements for performing moderately complex testing in the subspecialties of Hematology and Routine Chemistry. See D6065
D6065	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(b)(1)(2)(3)(4)(i) (b) Meet one of the following requirements: (b)(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located or have earned a doctoral, master's, or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; or (b)(2) Have earned an associate degree in a chemical, physical or biological science or medical laboratory technology from an accredited institution; or (b)(3) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(4)(i) Have earned a high school diploma or equivalent; and This STANDARD is not met as evidenced by: Based on record review, lack of documentation, the Laboratory Personnel Report (CMS-209) and an interview with the technical consultant (TC); the laboratory failed to ensure laboratory employees meet the education qualification requirements for performing moderately complex testing in the subspecialty and specialty of Routine Chemistry and Hematology, affecting 1 out of 2 testing personnel (TP). Findings: 1. The employee files and CMS-209 were reviewed. 2. The CMS 209 lists 2 TP (TP1 and TP2) performing Hematology and Routine Chemistry testing in the laboratory. 3. The employee files of TP1 and TP2 revealed the following: *TP1 and TP2 were authorized to perform patient testing; *TP2 failed to have their education credentials evaluated for United States equivalency. *The laboratory failed to ensure TP2 met the education requirement for performing moderately complex testing, prior to testing patients. 4. On a recertification survey conducted 09/04/2019 at 3:15 PM, the TC confirmed the above findings.
D6107	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(15) The laboratory director must specify, in writing, the responsibilities and duties of each consultant and each supervisor, as well as each person engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or result reporting and whether supervisory or director review is required prior to reporting patient test results. This STANDARD is not met as evidenced by: Based on record review, the Laboratory Personnel Report (CMS 209); the lack of documentation and an interview with the technical consultant (TC); the laboratory

	director (LD) failed to specify, in writing, the responsibilities and duties of each consultant and each supervisor, as well as each person engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or result reporting and whether supervisory or director review is required, in the specialties and subspecialties of Chemistry, General Immunology and Hematology, prior to reporting patient test results. Findings include: 1. The laboratory personnel documents, CMS 209, and manuals were reviewed. 2. The LD failed to assign the following the duties /responsibilities, in writing: *Technical Supervisor *Technical Consultant; and *General Supervisor 3. TP1, TP2, and TP3 were hired between October of 2018 and August of 2019. The LD failed to define, in writing, the following for the TP: *The procedures each individual is authorized to perform, *The duties the TP are to perform in the preanalytic, analytic, and postanalytic phases of testing; *Whether supervision is required for specimen processing, test performance or result reporting; and *Whether supervisory or director review is required, prior to reporting patients' test results. 4. On a recertification survey conducted 09/04/2019 at 3:15 PM, the TC confirmed the above findings.