Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	14D0892372	02/20/2018
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
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 the surveyor's review of the Laboratory Personnel Report (CMS 209), the policies, procedures, employee records, and an interview with the technical supervisor (TS); the laboratory failed to establish written policies and procedures that meet the personnel requirements in subpart M to assess employees performing moderately and highly complex testing, affecting 4 out of 4 testing personnel (TP). Findings: 1. The CMS 209 lists 4 TP performing Blood Chemistry, Hematology and General Immunology (both highly and moderately complex) testing in the laboratory. 2. The personnel files presented revealed that 4 out of 4 TP competencies did not indicate whether the TP were competent to perform the various tests conducted in the laboratory. 3. The competency procedure in-use is a check list of observations. There is no written indication on the 11 out of 11 competencies reviewed that the TP assessed had performed with "Satisfactory" or "Unsatisfactory" performances; or whether supervision or non-supervision is required for the assessed employee. 4. The laboratory's competency policy and step-by-step procedure does not include: b). Monitoring the recording and reporting of test results through document review (procedure only indicates observation of the TP recording and reporting); c). The review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records (not just the observing of the TP performing these functions); e). The assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency

	testing samples; and f). The assessment of problem solving skills, 5. On a Recertification survey conducted on February 20, 2018 at 2:00PM, the TS confirmed the above findings.
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: Based on the surveyor's review of the laboratory's College of American Pathologists (CAP) proficiency testing (PT) reports, laboratory records, manual, reports, and an interview with the technical supervisor (TS); the laboratory failed to verify the accuracy of the Synovial fluid and General Immunology testing it performs at least twice annually. Findings: 1. The laboratory's manual states that the laboratory will participate in the CAP-PT program for Special Immunology to fulfill the twice annual verification requirements for some of it's General Immunology tests. 2. The laboratory provided evidence of PT participation in the Special Immunology category for the following events: S2-C 2015; S2-A 2016; S2-B 2016; and S2-C 2016 for the following analytes: Anti-SSA/Ro autoantibodies (Anti-Sjgren ' s-syndrome-related antigen A); Anti-SSB/La autoantibodies (Anti-Sjgren ' s-syndrome-related antigen B); Anti-dsDNA (Anti-double stranded DNA) antibodies; Anti-nRNA (Anti-nuclear Ribonucleoprotein); Anti-Sm (Anti-Smith); and Anti-Centromere No documentation was provided as evidence that the laboratory verified the accuracy of it's Special Immunology testing during the year of 2017 to present. 3. No documented evidence was provided to show that the laboratory chose another method to verify the accuracy of its testing during 2017 when it did not participate in the CAP-PT program. 4. The laboratory also tests for the following special Immunology analytes which are not included in the CAP-PT program: Anti-Scl-70 (anti-topoisomerase I); Anti-Jo-1 antibodies; Anti-Histone; and Anti-Centromere B. The laboratory's method to verify the accuracy of these analytes are to take positive patient samples, freeze the samples, and retest them a week later 2 times, then analyze the results for accuracy and precision. The summary results provided from this method does not confirm the test systems accuracy. 5. The laboratory also test synovial fluid. The laboratory's manual does not define the method and procedure the laboratory will use to verify the accuracy of this test. No documentation was provided to show that the Uric Acid Crystal test had been verified for accuracy during the years of 2015, 2016 and 2017. 6. On a Recertification survey conducted on 02/20/2018 at 2:30 PM, the TS confirmed the above findings.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on the surveyor's review of the laboratory's manual, the Laboratory Personnel

	Report (CMS 209), and an interview with the technical supervisor (TS); the laboratory failed to establish and follow written procedures for all tests, assays, and examinations performed by the laboratory, affecting 90 patients. Findings: 1. The laboratory's procedures manual does not include a procedure for testing synovial fluid for Uric Acid crystals. 2. The CMS 209 lists 1 testing personnel performing Uric Acid Testing. 3. On a Recertification survey conducted on 02/20/2018 at 2:00 PM, the TS confirmed the above findings and stated that he thought Uric Acid testing was considered a Provider Performed Microscopy (PPM) test.
D6076	LABORATORY DIRECTOR CFR(s): 493.1441 The laboratory must have a director who meets the qualification requirements of 493. 1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart. This CONDITION is not met as evidenced by: Based on the surveyor's review of the laboratory personnel records and an interview with the technical supervisor (TS); the laboratory failed to have a director who meets the qualification requirements of 493.1405 and providing overall management and direction in accordance with 493.1407. Findings: 1. The laboratory failed to have a director who possesses a current State of Illinois Medical license. See D6003
D6078	LABORATORY DIRECTOR QUALIFICATIONS CFR(s): 493.1443 The laboratory director must be qualified to manage and direct the laboratory personnel and performance of high complexity tests and must be eligible to be an operator of a laboratory within the requirements of subpart R. (a) The laboratory director must possess a current license as a laboratory director issued by the State in which the laboratory is located, if such licensing is required; and (b) The laboratory director must-- (b)(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (b)(1)(ii) Be certified in anatomic or clinical pathology, or both, by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (b)(2) Be a doctor of medicine, a doctor of osteopathy or doctor of podiatric medicine licensed to practice medicine, osteopathy or podiatry in the State in which the laboratory is located; and (b)(2)(i) Have at least one year of laboratory training during medical residency (for example, physicians certified either in hematology or hematology and medical oncology by the American Board of Internal Medicine); or (b)(2)(ii) Have at least 2 years of experience directing or supervising high complexity testing; or (b)(3) Hold an earned doctoral degree in a chemical, physical, biological or clinical laboratory science from an accredited institution and-- (b)(3)(i) Be certified and continue to be certified by a board approved by HHS; or (b)(3)(ii) Before February 24, 2003, must have served or be serving as director of a laboratory performing high complexity testing and must have at least-- (b)(3)(ii)(A) Two years of laboratory training or experience, or both; and (b)(3)(ii)(B) Two years of laboratory experience directing or supervising high complexity testing. (b)(4) Be serving as a laboratory director and must have previously qualified or could have qualified as a laboratory director under regulations at 42 CFR 493.1415, published March 14, 1990 at 55 FR 9538, on or before February 28, 1992; or (b)(5) On or before February 28, 1992, be

	qualified under State law to direct a laboratory in the State in which the laboratory is located; or (b)(6) For the subspecialty of oral pathology, be certified by the American Board of Oral Pathology, American Board of Pathology, the American Osteopathic Board of Pathology, or possess qualifications that are equivalent to those required for certification. This STANDARD is not met as evidenced by: Based on the surveyor's review of the Laboratory Personnel Report (CMS 209), the laboratory personnel records and an interview with the technical supervisor (TS); the laboratory failed to have a laboratory director (LD) who possesses a current license issued by the State of Illinois. Findings: 1. The CMS 209 lists the employee on line 1 as the LD of the laboratory which performs moderately and highly complex testing. 2. The personnel file of the LD revealed that their State of Illinois Medical license to practice had expired 07/31/2017. 3 On a Recertification survey conducted on 02/20 /2018 at 2:15PM, the TS confirmed the above findings.
D6108	LABORATORY TECHNICAL SUPERVISOR CFR(s): 493.1447 The laboratory must have a technical supervisor who meets the qualification requirements of 493.1449 of this subpart and provides technical supervision in accordance with 493.1451 of this subpart. This CONDITION is not met as evidenced by: Based on the surveyor's review of the laboratory's records, manual, and an interview with the technical supervisor (TS); the TS failed to provide technical supervision in accordance with 493.1451 of this subpart in the specialty of Immunology, affecting 9776 tests. Findings: 1. The TS failed to resolve technical problems and ensure that remedial actions are taken whenever test systems deviate from the laboratory's established performance specifications. See D6118.
D6118	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(5) The technical supervisor is responsible for resolving technical problems and ensuring that remedial actions are taken whenever test systems deviate from the laboratory's established performance specifications. This STANDARD is not met as evidenced by: Based on the surveyor's review of the laboratory's records, manual, the Clinical Laboratory Improvement Amendment (CLIA) application (CMS 116), and an interview with the technical supervisor (TS); the TS failed to resolve technical problems and ensure that remedial actions are taken whenever test systems deviate from the laboratory's established performance specifications in the specialty of Immunology, affecting 9776 tests. Findings: 1. The TS failed to evaluate the non-scored results received from the proficiency testing (PT) program to determine the test system's performances during PT Events from 2015 through 2016, and, if applicable, establish corrective action, and assess possible affected patients. 2. The TS failed to establish a method to verify the accuracy of the Immunology test system for the analytes not included in the PT program panel. 3. The TS failed to provide corrective

	action and direction when the method used for biannual verification of the Immunology test system did not verify the system's accuracy. 4. On a Recertification survey conducted on 02/20/2018 at 2:30 PM, the TS confirmed the above findings.
D6134	CLINICAL CONSULTANT CFR(s): 493.1453 The laboratory must have a clinical consultant who meets the requirements of 493. 1455 of this subpart and provides clinical consultation in accordance with 493.1457 of this subpart. This CONDITION is not met as evidenced by: Based on the surveyor's review of the laboratory personnel records and an interview with the technical supervisor (TS); the laboratory failed to have a Clinical Consultant (CC) who meets the qualification requirements of 493.1417 and providing clinical consultation in accordance with 493.1419 of this part. Findings: 1. The laboratory failed to have a CC who possesses a current State of Illinois Medical license. See D6057.
D6135	CLINICAL CONSULTANT QUALIFICATIONS CFR(s): 493.1455 The clinical consultant must be qualified to consult with and render opinions to the laboratory's clients concerning the diagnosis, treatment and management of patient care. The clinical consultant must-- (a) Be qualified as a laboratory director under 493. 1443(b)(1), (2), or (3)(i) or, for the subspecialty of oral pathology, 493.1443(b)(6); or (b) Be a doctor of medicine, doctor of osteopathy, doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located. This STANDARD is not met as evidenced by: Based on the surveyor's review of the Laboratory Personnel Report (CMS 209), the laboratory personnel records and an interview with the technical consultant (TC); the laboratory failed to have a clinical consultant (CC) who possesses a current license issued by the State of Illinois. Findings: 1. The CMS 209 lists the employee on line 1 as the CC of the laboratory which performs moderately and highly complex testing. 2. The personnel file of the employee revealed that their State of Illinois Medical license to practice had expired 07/31/2017. 3 On a Recertification survey conducted on 02/20 /2018 at 2:15PM, the TS confirmed the above findings.