Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	14D0892372	09/03/2024
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
D2016	SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c) (a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history. This CONDITION is not met as evidenced by: Based on desk review of the Certification and Survey Provider Enhanced Reporting (CASPER) 0155D Individual Laboratory Profile report and College of Pathologists (CAP) proficiency testing (PT) records, the laboratory failed to participate in CAP PT event 2 of 2023 (See D2077) and for the analyte rheumatoid factor (RF) and the subspecialty of general immunology failed to achieve a satisfactory PT performance for two of three events in 2023 through 2024 (event 2 of 2023 & event 1 of 2024) resulting in an initial unsuccessful PT performance (See D2084 & D2085).
D2077	GENERAL IMMUNOLOGY

	CFR(s): 493.837(c) Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if-- (1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results; (2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and (3) The laboratory participated in the previous two proficiency testing events. This STANDARD is not met as evidenced by: Based on desk review of the Certification and Survey Provider Enhanced Reporting (CASPER) 0155D Individual Laboratory Profile report and College of Pathologists (CAP) proficiency testing (PT) records, the laboratory failed to participate in the diagnostic immunology CAP PT event 2 of 2023, resulting in a score of 0% for the testing event. Findings include: 1. Review of the CASPER 0155D report ran on 9-3-2024 identified the 0% scores for the specialty of general immunology and the analyte rheumatoid factor for event 2 of 2023. 2. Review of the CAP "S-B 2023 Diagnostic Immunology Original Evaluation" report (event 2 of 2023) dated 11/03/2024 stated, "[40] = Results for this kit were not received.".
D2084	GENERAL IMMUNOLOGY CFR(s): 493.837(f) Failure to achieve satisfactory performance for the same analyte or test in two consecutive testing events or two out of three consecutive testing events is unsuccessful performance. This STANDARD is not met as evidenced by: Based on desk review of the Certification and Survey Provider Enhanced Reporting (CASPER) 0155D Individual Laboratory Profile report and College of Pathologists (CAP) proficiency testing (PT) records, the laboratory failed to successfully participate in proficiency testing (PT) for the general immunology analyte rheumatoid factor (RF) during PT event 2 of 2023 and event 1 of 2024. Findings include: 1. Review of the CASPER 0155D report ran on 9-03-2024 identified the initial unsuccessful PT performance for the general immunology analyte RF. GENERAL IMMUNOLOGY RF - EVENT-2, 2023 = 0% - Unsatisfactory RF - EVENT-1, 2024 = 40% - Unsatisfactory 2. Review of the CAP PT evaluation reports confirmed the unsuccessful PT performance for RF during PT event 2 of 2023 and event one of 2024.
D2085	GENERAL IMMUNOLOGY CFR(s): 493.837(g) Failure to achieve an overall testing event score of satisfactory performance for two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.

	This STANDARD is not met as evidenced by: Based on desk review of the Certification and Survey Provider Enhanced Reporting (CASPER) 0155D Individual Laboratory Profile report and College of Pathologists (CAP) proficiency testing (PT) records, the laboratory failed to successfully participate in proficiency testing (PT) for the subspecialty of general immunology during PT event 2 of 2023 and event 1 of 2024. Findings include: 1. Review of the CASPER 0155D report ran on 9-03-2024 identified the initial unsuccessful PT performance for the general immunology subspecialty. GENERAL IMMUNOLOGY General Immunology - EVENT-2, 2023 = 0% - Unsatisfactory General Immunology - EVENT-1, 2024 = 40% - Unsatisfactory 2. Review of the CAP PT evaluation reports confirmed the unsuccessful PT performance for general immunology during PT event 2 of 2023 and event 1 of 2024.
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 a desk review of the Certification and Survey Provider Enhanced Reporting (CASPER) 0155D Individual Laboratory Profile report and the College of Pathologists (CAP) proficiency testing (PT) records, the laboratory director failed to ensure successful participation in an Health and Human Services (HHS) approved PT program for the subspecialty of general immunology (see D6087) resulting in the laboratory's initial unsuccessful PT performance for the subspecialty of general immunology and the analyte rheumatoid factor for two of the three PT events (event 2 of 2023 and event 1 of 2024).
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 a desk review of the Certification and Survey Provider Enhanced Reporting (CASPER) 0155D Individual Laboratory Profile report and ((CAP) Proficiency Testing (PT) records, the laboratory director failed to ensure the laboratory submitted PT results for diagnostic immunology event 2 of 2023 (See D2077); and failed to successfully participate in an Health and Human Services (HHS) approved PT program for the subspecialty of general immunology (See D2085) and the analyte rheumatoid factor (See D2084) resulting in the laboratory's initial unsuccessful PT performance for the subspecialty of general immunology and the analyte rheumatoid factor.