Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	24D0403111	11/06/2025
Name of Provider or Supplier	**Street Address, City, State**	
Arthritis And Rheumatology Consultants Pa	7600 France Ave S, Suite 5100, Edina, MN	

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	. The Arthritis and Rheumatology Consultants PA laboratory was found to be out of compliance with the regulations of the Clinical Laboratory Improvement Amendments of 1988 (42 C.F.R. part 493) upon completion of the recertification survey performed on November 6, 2025. The following standard-level deficiencies were cited: 493.1236 Evaluation of proficiency testing performance 493.1253 Establishment and verificaiton of performance specifications .
D5215	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(2) The laboratory must verify the accuracy of any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect laboratory test performance (that is, when the proficiency testing program does not obtain the agreement required for scoring as specified in subpart I of this part, or the laboratory receives a zero score for nonparticipation, or late return or results). This STANDARD is not met as evidenced by: . Based on document review and interview with laboratory personnel, the laboratory failed to verify the accuracy of six ungraded proficiency testing (PT) results for regulated and non-regulated analytes when the PT program did not obtain the agreement required for scoring in three of twelve proficiency testing events reviewed from 2024 and 2025. Findings are as follows: 1. The laboratory performed Chemistry and Immunology testing as confirmed by the General Supervisor (GS) during a tour of the laboratory at 10:07 on 11/6/25. 2. The laboratory performed PT using the American Proficiency Institute (API) provider. 3. Two Chemistry PT results were not graded due to result variance in 2025. Four Immunology PT results were not graded by API due to lack of consensus in 2024. See below. 2024 - Immunology 2nd Event Analytes: Anti-dsDNA, Anti-sm Sample ID: ANA-07 2024 Immunology 3rd Event Analyte: Anti-dsDNA, Anti-RNP/Sm Sample IDs: ANA-14, ANA-12 2025 - Chemistry 3rd Event Analyte: Bilirubin, Total Sample IDs: CH-12, CH-13 4.

	Evaluation of the ungraded results was not found in laboratory PT records. The laboratory was unable to provide this documentation upon request. 5. The laboratory was required to evaluate ungraded PT results as defined in the Proficiency Testing procedure found in LABDAQ software. 6. In an interview at 11:37 a.m on 11/6/25., the GS confirmed the above findings. .
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) (b) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (b)(1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (b)(1)(i)(A) Accuracy. (b)(1)(i)(B) Precision. (b)(1)(i)(C) Reportable range of test results for the test system. (b)(1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: . Based on observation, document review, and interview with laboratory personnel, the laboratory failed to complete one of five required performance verification (PV) activities for two Hematology analyzers implemented by the laboratory in 2024. Findings are as follows: 1. The laboratory performed Erythrocyte Sedimentation Rate (ESR) testing under the Hematology specialty as confirmed by the General Supervisor (GS) during a tour of the survey at 10:07 on 11/6/25. 2. An Alcor iSED and and Alcor miniiSED were observed as present and available for use during the tour. The laboratory performed ESR testing on these analyzers beginning in October 2024. 3. The laboratory was required to perform reportable range verification when adding a new analyzer as defined in the Implementation of New Tests procedure found in the LABDAQ software. 4. Reportable range verification documentation was not included with the PV activities found in the Alcor Validation binder provided by the laboratory on the date of survey. The laboratory was unable to produce the missing documentation upon request. 5. In an interview at 2:28 p.m. on 11/6/25, the GS confirmed the above findings. 6. In an email received at 10:06 a.m. on 11/7/25, the GS indicated the laboratory performed the following testing on the Alcor Hematology analyzers: Year Instrument # of ESR tests 2024 miniiSED 136 2024 iSED 1719 2025 miniiSED 782 2025 iSED 11,199 .