Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	03D0969376	07/13/2026
Name of Provider or Supplier	**Street Address, City, State**	
Arizona Arthritis & Rheumatology Associates	5681 W Beverly Lane Ste 101, Glendale, AZ	

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	An recertification survey was performed on July 13, 2026. The facility was found to be NOT in compliance with the following CLIA conditions for specialties /subspecialties surveyed for 42 CFR: 493.1487 - Laboratory Testing Personnel (High Complexity)
D6046	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8) (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. The procedures for evaluation of the competency of the staff must include, but are not limited to-- This STANDARD is not met as evidenced by: Based on review of 2026 competency evaluation documentation, review of the CMS-209, Laboratory Personnel form, review of patient test reports and interview with the technical consultant (TC) on 7/13/26 at 11:00 AM, the technical consultant failed to perform an annual competency evaluation for TP-2 in 2026, specific to testing performed on the Gold Standard Diagnostics Thunderbolt analyzer. Findings include: 1. Annual competency documentation reviewed for TP-2 from 1/06/26 revealed the competency evaluation was performed to assess the competency of a CLA (Certified Lab Assistant), not a testing personnel. The CLA competency form included only the evaluation of: "1.) Direct observation of routine patient preparation, if applicable, specimen handling, processing and testing; 2.) Completion of instrument maintenance as permitted; and 3.) Review of CLA efficiency and performance." 2. The CMS-209, Laboratory Personnel form presented for review on 7/13/26 listed 3 testing personnel including TP-2 who is listed as a testing personnel for moderate complexity testing. 3. Patient test reports reviewed during the survey indicated that TP-2 performed moderate complexity testing as follows: - Anticitrulline Ab (CCP) testing performed by TP-2 on 9/18/25 on the Gold Standard Diagnostics Thunderbolt analyzer (Patient

	#2) - Anti-DNA (dsDNA) testing performed by TP-2 on 2/20/26 on the Gold Standard Diagnostics Thunderbolt analyzer (Patient #3) 4. The TC interviewed on 7/13/26 at 11: 00 AM acknowledged that the competency evaluation documentation for TP-2 from 1 /06/26 failed to evaluate the competency of TP-2 for moderate complexity testing as required under 493.1413(b)(i) through 493.1413(b)(vi).
D6122	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(8)(ii) (b)(8)(ii) Monitoring the recording and reporting of test results; This STANDARD is not met as evidenced by: Based on review of semiannual competency evaluations from December 2024, review of 2 out of 2 patient test reports for testing performed on the Quanta-Lyser 3000 analyzer and interview with the Technical Supervisor (TS) on 7/13/26 at 11:00 AM, the TS failed to evaluate the recording and reporting of test results generated from the Quanta-Lyser 3000 analyzer during the semiannual competency evaluation for 1 out of 3 testing personnel (TP-2) who perform high complexity testing in the subspecialty of general immunology. Findings include: 1. The laboratory began high complexity testing in the subspecialty of general immunology on the Quanta-Lyser 3000 analyzer in June 2024, with a reported annual test volume of 694,572. 2. The annual competency evaluation completed by the TS on 12/05/24 for TP-2 for testing performed on the Quanta-Lyser 3000 analyzer failed to include the evaluation of recording and reporting of test results. 3. Review of the personnel records for 1 out of 3 testing personnel revealed the laboratory failed to have academic credentials to qualify TP-2 for high complexity testing performed on the Quanta-Lyser 3000 analyzer. See D6171 4. Two out of two patient test reports (Patient #2 and Patient #3) from the Quanta-Lyser 3000 analyzer revealed TP-2 performed and resulted patient testing on 2/24/26 and 9/18/25. 5. TS interviewed on 7/13/26 at 11:00 AM acknowledged the competency evaluation referenced above for TP-2 listed "N/A" for monitoring the recording and reporting of test results on the Quanta-Lyser 3000 analyzer.
D6125	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(8)(v) (b)(8)(v) Assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples; and This STANDARD is not met as evidenced by: Based on review of semiannual competency evaluations from December 2024, review of 2 out of 2 patient test reports for testing performed on the Quanta-Lyser 3000 analyzer and interview with the Technical Supervisor (TS) on 7/13/26 at 11:00 AM, the TS failed to evaluate the assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples during the semiannual competency evaluation for 1 out of 3 testing personnel (TP-2) who perform high complexity testing in the subspecialty of general immunology. Findings include: 1. The laboratory began high complexity testing in the subspecialty of general immunology on the Quanta-Lyser 3000 analyzer in June 2024, with a reported annual test volume of 694,572. 2. The semiannual competency evaluation completed by the TS on 12/05/24 for TP-2 for testing performed on the

	Quanta-Lyser 3000 analyzer failed to include the assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples. 3. Review of the personnel records for 1 out of 3 testing personnel revealed the laboratory failed to have academic credentials to qualify TP-2 for high complexity testing performed on the Quanta-Lyser 3000 analyzer. See D6171 4. Two out of two patient test reports (Patient #2 and Patient #3) from the Quanta-Lyser 3000 analyzer revealed TP-2 performed and resulted patient testing on 2/24/26 and 9/18/25. 5. TS interviewed on 7/13/26 at 11:00 AM acknowledged the competency evaluation indicated above for TP-2 listed "N/A" for the assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples on the Quanta-Lyser 3000 analyzer.
D6168	TESTING PERSONNEL CFR(s): 493.1487 The laboratory has a sufficient number of individuals who meet the qualification requirements of 493.1489 of this subpart to perform the functions specified in 493. 1495 of this subpart for the volume and complexity of testing performed. This CONDITION is not met as evidenced by: Based on review of personnel records and interview with the Technical Supervisor (TS) on 7/13/26 at 1:00 PM, the laboratory failed to have academic credentials required to qualify one out of three testing personnel for high complexity testing in the subspecialty of General Immunology. (Refer to D6065).
D6171	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1489(b) (b) Meet one of the following requirements: (b)(1) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; or (b)(2)(i) Have earned a doctoral, master's, or bachelor's degree in a chemical, biological, clinical or medical laboratory science, or medical technology from an accredited institution; or (b)(2)(ii) Be qualified under the requirements of 493.1443(b)(3) or 493.1449(c)(4) or (5); or (b)(3)(i) Have earned an associate degree in a laboratory science or medical laboratory technology from an accredited institution or (b)(3)(ii) Have education and training equivalent to that specified in paragraph (b)(2)(i) of this section that includes (b)(3)(ii)(A) At least 60 semester hours, or equivalent, from an accredited institution that, at a minimum, includes either (b)(3)(ii)(A)(1) 24 semester hours of medical laboratory technology courses; or (b)(3)(ii)(A)(2) 24 semester hours of science courses that include (b)(3)(ii)(A)(2)(i) 6 semester hours of chemistry; (b)(3)(ii)(A)(2)(ii) 6 semester hours of biology; and (b)(3)(ii)(A)(2)(iii) 12 semester hours of chemistry, biology, or medical laboratory technology in any combination; and (b)(3)(ii)(B) Have laboratory training that includes: (b)(3)(ii)(B)(1) Completion of a clinical laboratory training program approved or accredited by the ABHES or the CAAHEP (this training may be included in the 60 semester hours listed in paragraph (b)(3)(ii)(A) of this section); or (b)(3)(ii)(B)(2) At least 3 months documented laboratory training in each specialty in which the individual performs high complexity testing; or (b)(4) Successful completion of an official U.S. military medical laboratory procedures training course of at least 50 weeks duration and having held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or

	(b)(5) Notwithstanding any other provision of this section, an individual is considered qualified as a high complexity testing personnel under this section if they were qualified and serving as a high complexity testing personnel in a CLIA-certified laboratory as of December 28, 2024, and have done so continuously since December 28, 2024. (b)(6) For blood gas analysis (b)(6)(i) Be qualified under paragraph (b)(1), (2), (3), (4), or (5) of this section; or (b)(6)(ii) Have earned a bachelor's degree in respiratory therapy or cardiovascular technology from an accredited institution; or (b)(6)(iii) Have earned an associate degree related to pulmonary function from an accredited institution. (b)(7) For histopathology, meet the qualifications of 493.1449 (b) or (f) to perform tissue examinations. This STANDARD is not met as evidenced by: Based on review of personnel records, review of patient test reports for immunology testing performed on the Quanta-Lyser 3000 analyzer and interview with Technical Supervisor (TS) on 7/13/26 at 1:00 PM, the laboratory failed to provide documentation of academic credentials to qualify one out of three testing personnel (TP-2) for high complexity testing in the subspecialty of General Immunology. Findings include: 1. The laboratory began testing on the Quanta-Lyser 3000 analyzer in June 2024 and performs the following tests: RNP (Ribonucleoprotein) antibody, ANA (antinuclear antibody) screening and ANCA Vasculitides (Anti-neutrophil cytoplasmic autoantibody). The laboratory's reported test volume in the subspecialty of General Immunology is 694,572. 2. Review of personnel records for 1 out of 3 testing personnel revealed the laboratory failed to have academic credentials to qualify TP-2 for high complexity testing performed on the Quanta-Lyser 3000 analyzer. 3. Two out of two test reports for RNP testing indicated the RNP tests were performed by TP-2 as follows: Patient #2 performed on 9/18/25 and Patient #3 performed on 2/24/26. 4. The TS interviewed on 7/13/26 at 1:00 PM confirmed the laboratory failed to provide the required academic documentation to qualify TP-2 for high complexity testing, and acknowledged that TP-2 had performed patient testing on the Quanta-Lyser 3000 analyzer.