

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 31D0113101	(X3) Date Survey Completed 08/19/2026
Name of Provider or Supplier Rheumatology Assocs Of North Jersey	Street Address, City, State 1415 Queen Anne Road, Teaneck, NJ	
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
D5213	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(1) (b) The laboratory must verify the accuracy of the following: (b)(1) 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 surveyor review of the American Association of Bioanalysts Medical Laboratory Evaluation (AAB-MLE) Proficiently Testing (PT) records and interview with the Technical Consultant (TC) the Laboratory Director (LD) failed to ensure that the laboratory participated in an accurate split sample assessment for Hematology testing. from 6/11/24 to 8/19/26. The findings include: 1. A review of AAB-MLE PT events 3-2024, 1,2,3-2025 and 1-2026 revealed that the laboratory did not verify accuracy of the following analytes. a) Granulocytes absolute (GRA#) b) Monocytes absolute (MON#) c) Lymphocytes Absolute (LYM#) 2. The TC confirmed on 8/19/26 at 11:00 am that the LD did not ensure the laboratory participated in an accurate split sample assessment for the above mentioned tests.
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 surveyor review of the Proficiency Testing (PT) records and interview with the Technical Consultant (TC), the laboratory failed to verify the accuracy of Folate (FOL) results obtained from the American Proficiency Institute (API) for the Chemistry-Core 2nd event of 2025. The findings include: 1. The laboratory received a score of 100%, but received a code "Not Graded - 9" for FOL samples IA-07, and 9. 2. API reported the range for FOL sample IA-07 as 3.7 - 7.1 ng/dL. 3. The laboratory reported FOL Sample IA-07 as out of range with >20 ng/dL. 4. API reported the range for FOL sample IA-09 as 5.2 - 9.7 ng/dL . 5. The laboratory reported FOL Sample IA-09 as out of range with >20 ng/dL. 6. The laboraotry reported FOL sample IA-08 as "Lab reported test problem" no result was submitted. 7. The laboratory obtained a 40% for FOL 2nd event of 2025 with API. 8. The TC confirmed on 8/19/26 at 10:20 am, the accuracy of the PT results were not verified.
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 surveyor review of the Procedure Manual (PM), Proficiency Testing (PT) records and interview with the Techincal Consultant (TC), the laboratory failed to verify the accuracy and reliability of Immunology testing performed on the Dynex DSX from 6/11/24 to 8/19/26. The finding includes: 1. Surveyor review of PT records revealed all analytes tested by the laboratory were not included in any PT events in the calendar years 2024, 2025. 2. The following alaytes were not verified for accuracy twice annually on the Dynex DSX analyzer: a) anti-single-stranded DNA (ssDNA) b) anti-double-stranded DNA (dsDNA) c) anti-Smith (Sm) d) Ribonucleoprotein / Smith (RNP/Sm) e) Anti-Sjgren's Syndrome A (SSA) f) Anti-Sjgren's Syndrome B (SSB) g) Chromatin h) scleroderma-70 (Scl-70) i) Centromere j) Anti-Cardiolipin ab k) anti-Beta 2 Glycoprotien 3. The TC confirmed 8/19/26 at 1:00 pm, the laboratory did not verify the accuracy for Immunology testing performed on the Dynex DSX.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) (b) The procedure manual must include the following when applicable to the test procedure: (b)(1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (b)(2) Microscopic examination, including the detection of inadequately prepared slides. (b)(3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (b)(4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (b)(5) Calibration and calibration verification procedures. (b)(6) The reportable range for test results for the test system as established or verified in 493.1253. (b)(7) Control procedures. (b)(8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (b)(9) Limitations in the test methodology, including interfering substances. (b)(10) Reference intervals (normal values). (b)(11) Imminently life-threatening test results, or panic or alert values. (b)(12) Pertinent literature references. (b)(13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life

	threatening results, or panic, or alert values. (b)(14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based surveyor review of the Procedure Manual (PM), and interview with the Technical Consultant (TC) the laboratory failed to have a complete procedures for Immunology tests from 6/29/2022 to the 8/19/26. The findings include: 1. There was no procedure to verify the accuracy at least twice annually non regulate analytes run on the Dynex DSX analyzer. 2. The TC confirmed on 8/19/26 at 11:25 am that the laboratory PM did not have the aforementioned procedures.
D5775	COMPARISON OF TEST RESULTS CFR(s): 493.1281(a)(c) (a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. This STANDARD is not met as evidenced by: Based on surveyor review of the Laboratory Records and interview with the Technical Consultant (TC), the laboratory failed to perform correlation studies for Immunology tests performed on the Dynex DSX analyzers twice per year from 6/11/24 to 8/19/24. The finding includes: 1) There was no documented evidence that a correlation study was performed. 2) The TC confirmed on 8/19/26 at 11:00 am that the laboratory did not perform a correlation study twice a year.
D5891	POSTANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1299(a) (a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess and, when indicated, correct problems identified in the postanalytic systems specified in 493.1291. This STANDARD is not met as evidenced by: Based on surveyor review of the Procedure Manual (PM) and interview with the Technical Consultant (TC), the laboratory failed to establish a procedure for periodically verifying the accuracy of calculated data by the Lab Information System (LIS) from 6/11/24 to 8/19/24. The finding includes. 1. The laboratory did not have a procedure for verifying Estimated Glomular Filtration Rate (eGFR), BUN/creatinine, Globulin calculations by the LIS. 2. The TC confirmed on 8/19/26 at 12:00 pm, the laboratory did not have a procedure to verify the accuracy of calculated data by the LIS.