Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	31D0113101	06/11/2024
Name of Provider or Supplier	**Street Address, City, State**	
Rheumatology Assocs Of North Jersey	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
D5221	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d) All proficiency testing evaluation and verification activities must be documented. This STANDARD is not met as evidenced by: Based on surveyor review of Proficiency Testing (PT) results and interview with the General Supervisor (GS), the laboratory failed to review coded results for Celiac Serology testing performed with the College of American Pathologists (CAP) in 2023. The findings include: 1. The laboratory received a coded result "see note 27" for Celiac Serology event CES-A 2023 for Anti-gliadin IgG, specimen CES-02 and CES-03. 2. The laboratory received a coded result "see note 26" for Celiac Serology event CES-A 2023 for Anti-tTG IgA, Qual specimen CES-01, 02, and 03. 3. There was no documented evidence that coded PT results were reviewed. 4. The GS confirmed on 6 /11/2024 at 1:15 pm that the laboratory did not review coded PT results. .
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (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. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in

	the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (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. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on the lack of a Procedure Manual (PM), and interview with the General Supervisor (GS) the laboratory failed to have a complete procedures for Chemistry, Immunology and Mycobacteriology tests from 6/29/2022 to the date of survey. The findings include: 1. There were no Quality Control procedures. 2. There was no procedure that defined Imminently life-threatening test results, or panic or alert values 3. There were no procedures for specimen collection, labeling, storage and criteria for specimen acceptability and rejection 4. There were no procedures for test calculations and interpretation of results. 5. There were no procedures for the course of action to take if a test system becomes inoperable. 6. There were no procedures for reporting tuberculosis test results to the state of New Jesrey. 7. There was no procudre for bi-annual method comparison. 8. The GS confirmed on 6/11/2024 at 11:25 am that the laboratory failed to have a PM with the aforementioned procedures..
D5779	CORRECTIVE ACTIONS CFR(s): 493.1282(a) Corrective action policies and procedures must be available and followed as necessary to maintain the laboratory's operation for testing patient specimens in a manner that ensures accurate and reliable patient test results and reports. This STANDARD is not met as evidenced by: Based on the lack of a Procedure Manual (PM), and interview with the General Supervisor (GS) the laboratory failed to have available Corrective Action (CA) procedures to maintain the laboratory's operation for testing patient specimens in a manner that ensures accurate and reliable patient test results and reports on the date of survey. The GS confirmed on 6/11/2024 at 1:00 pm that the laboratory failed to have available CA procedures.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (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 analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on surveyor review of the Procedure Manual and interview with General Supervisor (GS) the laboratory failed to establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems on the date of survey. The findings include: 1. The laboratory did not have a policy with criteria on when to repeat a

	patient test. 2. The laboratory failed to have a procedure to verify new lots of controls before they were put in use. 3. The Laboratory failed to have a procedure on how Quality Control is reviewed, monitored and maintained. 4. The GS confirmed on 6/11 /2024 at 11:45 am that the laboratory failed to establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems.
D6013	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(ii) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(3) Ensure that-- (e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method; This STANDARD is not met as evidenced by: Based on surveyor review of the Performance Specification (PS) records and interview with the General Supervisor (GS) the Laboratory Director (LD) failed to ensure that PS procedures performed for Chemistry testing performed on the Vitros 5600 analyzer were adequate from February 2023 to the date of survey. The findings include: 1. There was no documented evidence that a normal patient range study was performed prior to the start of patient testing. 2. The GS confirmed on 6/11/2024 at 11: 15 am that PS records were not adequate.
D6030	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(12) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(12) Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills; This STANDARD is not met as evidenced by: Based on surveyor review of the Competency Assessment (CA) records, the lack of a Procedure Manual (PM) and interview with the General Supervisor (GS) the Laboratory Director (LD) failed to have established written procedures for assessing the competency of Testing Personnel (TP) from 6/29/22 to the date of survey. The findings include: 1. There was no written procedure or policy for how to assess the competency of new employees and the annual competency of TP. 2. The GS confirmed on 6/11/2024 at 10:30 am the LD failed to establish written policies and procedures for CA.

D6074	TESTING PERSONNEL RESPONSIBILITIES CFR(s): 493.1425(b)(5) Each individual performing moderate complexity testing must be capable of identifying problems that may adversely affect test performance or reporting of test results and either must correct the problems or immediately notify the technical consultant, clinical consultant or director. This STANDARD is not met as evidenced by: Based on the surveyor review of Quality Control (QC) records and interview with the General Supervisor (GS), the Laboratory Director (LD) failed to identify problems that may affect test performance by not reviewing and evaluating trends and/or shifts for tests performed on the Dynex DSX Automated ELISA Processor analyzer from 6 /29/22 to the date of survey. The GS confirmed on 6/11/2024 at 1:35 pm that trends and shifts were not reviewed.