Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	31D0113101	04/03/2019
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
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. This STANDARD is not met as evidenced by: Based on surveyor review of Quality Control Results (QCR), observation in the Sysmex xp 300 analyzer and interview with the General Supervisor (GS), the laboratory failed to retain all unaccepted QCR from 11/28/17 to the date of survey. The GS confirmed on 4/3/19 at 1:15 pm tha all unaccepted QCR were not retained.
D5211	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a) The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part. This STANDARD is not met as evidenced by: Based on surveyor review of the Proficiency Testing (PT) records and interview with the General Supervisor (GS), the laboratory failed to evaluate coded results obtained in CES-B 2018 Celiac Serology event with the College of American Pathologists (CAP). The findings include: 1. The laboratory did not evaluate Code 27 (lack of participant or referee consensus) and Code 26 (educational challenge) obtained in CES-B 2018 event. 2. The GS confirmed on 4/3/19 at 11:30 am that the laboratory failed to evaluate coded results for PT events in 2018.
D5309	TEST REQUEST

	CFR(s): 493.1241(e) If the laboratory transcribes or enters test requisition or authorization information into a record system or a laboratory information system, the laboratory must ensure the information is transcribed or entered accurately. This STANDARD is not met as evidenced by: Based on review of Test Requisition (TR), Laboratory Information System (LIS) and interview with the General Supervisor (GS), the laboratory failed to ensure that information from TR was transcribed accurately into the LIS for all tests from11/28 /17 to the date of the survey. The GS confirmed on 4/3/19nat 1:15 pm that the laboratory did not ensure information was transcribed accurately.
D5391	PREANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1249(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 preanalytic systems specified at 493.1241 through 493.1242. This STANDARD is not met as evidenced by: Based on surveyor review of the Procedure Manual (PM) and interview with the General Supervisor (GS), the laboratory failed to established a written procedure on how transcribed information from test requisition into the laboratory information system will be monitored from 11/28/17 to the date of survey. The GS confirmed on 4 /3/19 at 1:00 pm that the laboratory did not have the procedure mentioned above.
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: Based on surveyor review of the Manufacturer's Pakage Insert (MPI), Final Report and interview with the General Supervisor (GS) on phone, the laboratory failed to follow MPI instruction for interpreting and reporting results from August 2018 to the date of survey. The finding includes: 1. Section Calculation and Test Interpretation, second paragraph stated concentration greater than 10 IU/ml reported as >10 but the laboratory reported for patient # 16974, >13.733 Mitogen value. 2. The GS confirmed on phone 4/3/19 that the laboartory did not follow MPI instructions.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions;

	(b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: Based on lack of Calibration Verification (CV) records and interview with the General Supervisor (GS), the laboratory failed to perform and document CV procedures at least once every six months for endocrinology tests performed on Access 2 from 11/28 /17 to the date of survey. The GS confirmed on 4/3/19 at 1:50 pm that CV was not performed every six months for tests performed on Access 2 analyzer.
D5449	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on lack of the Quality Control (QC) records and interview with the General Supervisor (GS), the laboratory failed to perform and document quality control for QuantiFERON-TB Gold Plus test from August 2018 to the date of the survey. The finding includes: 1. The laboratory did not perform positive and negative QC on each day of patient testing. 2. The laboratory ran and reported around six patient samples a week. 3. The GS confirmed on 4/3/19 at 1:15 pm that the laboratory did not perform and document quality control on each day of patient testing.
D5469	CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- Establish or verify the criteria for acceptability of all control materials. (i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (ii) The laboratory may use the stated value

	of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on surveyor review of the Quality Control (QC) records and interview with the General Supervisor (GS), the laboratory failed to verify that the assayed QC materials were within the acceptable ranges before they were put into use for tests performed on the Access 2, ACL-Alere, DSX and iSED analyzers from 11/28/17 to the date of survey. The GS confirmed on 4/3/19 at 12:30 pm that the laboratory did not verify QC materials for tests performed in the laboratory.
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 (PM), Quality Control (QC) records and interview with the General Supervisor (GS), the laboratory failed to establish a procedure to verify new QC material used in Endocrinology, Routine Chemistry and Hematology tests before put in use from 11/28/17 to the date of the survey. The GS confirmed on 4/3/19 at 12:10 pm the laboratory did not have a procedure to verify new QC material.
D5891	POSTANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1299(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: a) Based on surveyor review of the Procedure Manual and interview with the General Supervisor (GS), the laboratory failed to have a procedure to verify interfaced and calculated results into the laboratory information system from 11/28/17 to the date of the survey. The GS confirmed on 4/3/19 at 1:15 pm that the laboratory did not have the procedure mentioned above. b) Based on surveyor review of the Final report (FR) and interview with the GS, the laboartory failed to identify problem on FR from 11/28 /17 to the date of survey. The finding includes: 1. The "Receive On" date of specimen was after the result "Reported On" date. 2. The GS confirmed on 4/3/19 at 2:00 pm the the laboratory did not identify FR problem. c) Based on surveyor review of Mycobateriology Final report, Manufacturer's Package Instructions (MPI) and interview with the GS on phone, the laboratory failed to identify problem on FR from

	August 2018 to the date of survey. The finding includes: 1. The laboratory reported 'Expected Values' for TB test but there were no expected values for the test in the MPI. 2. The GS confirmed on phone 4/3/19 at 2:00 pm the laboratory did not identify problem in reporting.
D6018	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iii) 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)(4)(iii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action; This STANDARD is not met as evidenced by: Based on surveyor review of the Proficiency Testing (PT) records and interview with the General Supervisor (GS), the Laboratory Director failed to ensure that PT results obtained from the American Proficiency Institute (API) were reviewed and evaluated by the appropriate staff in the calendar year 2018. The finding includes: 1. There was no review on API results for Hematology/Coagulation events 2 and 3 of 2018. 2. The GS confirmed on 4/3/19 at 10:10 am that the laboratory did not review and evaluate PT results.
D6029	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(11) 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)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results. This STANDARD is not met as evidenced by: Based on surveyor review of the Personnel Files and interview with the General Supervisor (GS), the Laboratory Director failed to have foreign education evaluated for one out of three Testing Personnel (TP) from 11/28/17 to the date of the survey. The GS confirmed on 4/3/19 at 11:40 am that all TP did not have education records.
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 Procedure Manual and interview with the General Supervisor (GS), the Laboratory Director (LD) failed to establish a Competency Assessment (CA) procedure with the required elements from 11/28/17 to the date of the survey. The GS confirmed on 4/3/19 at 11:40 am that a CA procedure was not established.