Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	33D0162274	03/27/2023
Name of Provider or Supplier	**Street Address, City, State**	
Center For Rheumatology Llp,The	4 Tower Place, 8th Floor, Albany, NY	

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
D2015	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6) (5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event. This STANDARD is not met as evidenced by: Based on review of the third event 2020, all three events of 2021 and 2022, American Proficiency Institute (API) records and attestation forms, analyzer printouts, API test result forms and API summary test reports, the laboratory failed to maintain signed copies of the attestation forms and API test summary reports. FINDINGS: 1. The laboratory director failed to sign and date the attestation forms for the following test events: a. Third event of 2020; first and third event of 2021; all three events in 2022; and first event of 2023. 2. The testing person #1 confirmed during interview on 3/27 /2023 at 11:00 A.M. that the laboratory director failed to sign and date the attestation forms.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable,

	consultant competency. This STANDARD is not met as evidenced by: Based on review of the personnel files for testing personnel #1 and #2, lack of six-month and annual competency evaluation, SOP for competency evaluation and an interview with testing person #1, the laboratory director failed to follow the establish competency evaluation policy regarding the six-month and annual for the first year of employment. FINDINGS: 1. The Competency evaluation policy states, "Each individual performs require a degree of skill commensurate with the individual's education, training or experience, and technical abilities. o Follow the laboratory's procedures for specimen handling and processing, test analyses, reporting and maintaining records of patient test results. o Maintain records that demonstrate that proficiency testing samples are tested in the same manner as patient samples. o Adhere to the laboratory's quality control policies, document all quality control activities, instrument and procedural calibrations and maintenance performed. o Follow the laboratory's established corrective action policies and procedures whenever test systems are not within the laboratory's established acceptable levels of performance. o 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 director. o Document all corrective actions taken when test systems deviate from the laboratory's established performance specifications. 2. Lack of six-month and annual competency evaluation for testing person #1 hired 11/29/21 for their first year of employment. 3. Testing person # 1 confirmed on 3/27/23 at 9:30 AM, the laboratory director did not perform the six-month and annual competency.
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 review of the third event 2020, all three events of 2021 and 2022 API summary test reports, the laboratory failed to maintain a signed copy of the API test summary reports. FINDINGS: 1. The laboratory director failed to review, sign and date the API PT summary reports for the following test events: a. third event of 2020; 1st & 3rd events of 2021 and 1st & 2nd events of 2022. 2. The testing person #1 confirmed during interview on 3/27/2023 at 11:00 am, the laboratory director failed to review, sign and date the API PT summary reports.
D5291	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(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 general laboratory systems requirements specified at 493.1231 through 493.1236. This STANDARD is not met as evidenced by: Based on review of the monthly Quality Assessment (QA) documentation for 2020,

	2021, 2022 and January & February 2023, the laboratory failed to follow their established QA policy. FINDINGS: 1. The QA states, "that a monthly review of temperature logs, personnel competency, QC & calibration for the hematology analyzer, laboratory failures/error-corrective action, LIS system (annually), test requisition/reports- patient chart review (5 charts bi-annually), SOP (annually), complaint and communication, safety, and API PT records., using a detail checklist sheet." 2. The laboratory failed to identify the following error/issues and take corrective action: a. The laboratory director failed to sign and date the attestation forms for the following test events third event of 2020; first and third event of 2021; all three events in 2022; first event of 2023 b. The laboratory director failed to review, sign and date the API PT summary reports for the following test events third event of 2020; first and third events of 2021 and first and second events of 2022. c The laboratory failed to use a currently calibrated thermometer for room temperature and humidity in the laboratory area.. d. The laboratory failed to perform a verification of current lot number to new lot number of the hematology controls performed on the Sysmex XN-530. e. The laboratory director failed to perform and document a six-month and annual competency evaluation for the testing person #1 for their first year of employment.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on review of the laboratory area room temperature/humidity logs for calendar years 2020,2021,2022 through survey date, the Temperature SOP and an interview with the testing person #1, the laboratory failed to use a currently calibrated thermometer. FINDINGS: 1. The Thermo Fisher Hydroban (S/N 191922824) digital thermometer located in the laboratory where the hematology tasting is performed indicated a calibration date of 1/30/2021, therefore, the thermometer used to record the laboratory's room temperature and humidity was out of calibration from 11 /02/21 through survey date. 2. The testing person #1 confirmed on 3/27/23 at 10:00 AM, the surveyor's findings regarding the respective thermometer being out of calibration, since 1/31/2021. Recommendation to change the log sheet for room temperature from C to F. The nursing staff in the infusion area record the temperatures daily. Not all the log sheets had the temperature range recorded on them. The lab stores control, calibration material and API PT samples in refrigerator/freezer #1 and pharmaceuticals material in #2 refrigerator/freezer. The thermometer used to record the #1 temperatures did not have a calibration date, nor did the laboratory have a packet/insert or invoice for that thermometer. Therefore, surveyor could not determine if the thermometer was out of calibration. Recommendation was made to replace it. The two refrigerator/freezer do have an alarm system. THIS IS A RECITED DEFICIENCY FROM THE SURVEY CONDUCTED ON NOVEMBER 18, 2020.
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 review of the laboratory's Quality Control (QC) records, the laboratory failed to perform a verification of current lot number to new lot number of the hematology controls performed on the Sysmex XN-530. FINDINGS: 1. The new QC lot to lot validation documentation for the analyzer was not available upon request during the survey since the analyzer's implementation date to survey date of 6/1/21. 2. The testing person #1 confirmed during interview on 3/27/2023 at 10:45 am, the new lot to lot validation of QC material for hematology analyzer was not performed.
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: Based on review of the laboratory procedure manual, QC records, QA documentation and confirmed in an interview with testing person #1, the director failed to provide overall management for all phases of moderate complexity testing. FINDINGS: The laboratory director failed to ensure that the laboratory: 1. Reviewed the API PT summary reports, refer to D6018. 2. Maintained the QC program for Completed Blood Count (CBC), refer to D6020. 3. Maintained the written QA policy for all phases of laboratory testing, refer to D6021. 4. Performed the six-month competency evaluation for the newly hired testing person, refer to D6053. 5. Performed the annual review for the newly hired person, refer to D6054.
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 the review of API PT summary reports, and an interview with the testing person #1, the laboratory director failed to review the scored proficiency testing reports received from API to evaluate the laboratory's performance. Refer to D2015 and D5211 .
D6020	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) 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)(5) Ensure that the quality control program is established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on review of Sysmex XN 530 operations manual, laboratory QC records, and an interview with the testing person #1, the laboratory director failed to maintain the hematology QC program to assure the quality of laboratory services. Refer to D5469.
D6021	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) 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)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on review of the laboratory's QA policy, QA documentation, and an interview with testing person #1, the laboratory director failed to follow the established QA procedure for maintaining a mechanism to monitor, assess, and when detected, correct problems identified in the general laboratory system. Refer to D5209, D5211, D5291, D5413, D5469
D6053	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: Based on review of the Competency Evaluation policy, personnel file records, lack of

	competency evaluation records for the testing person #1 and confirmed in an interview with testing person #1, the laboratory director, failed to perform the six-month competency evaluation for the new testing person during the first year of patient testing. Refer to D5209.
D6054	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year. This STANDARD is not met as evidenced by: Based on a review of the Competency assessment policy, lack of competency evaluations records for testing person #1, and confirmed in an interview with the testing person #1, the laboratory director, acting as the technical consultant, failed to assess the testing person#1 in calendar year 2022. Refer to D5209.