

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 33D0162274	(X3) Date Survey Completed 08/13/2025
Name of Provider or Supplier Center For Rheumatology Llp,The	Street Address, City, State 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
D2014	<p>TESTING OF PROFICIENCY TESTING SAMPLES</p> <p>(b)(6) 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.</p> <p>This STANDARD is not met as evidenced by: Based on review of Proficiency Testing (PT) records, as well as interviews with the Clinical Director (CD) and Testing Personnel (TP), the laboratory failed to complete the attestation statement provided by the PT program, signed by the analyst and Laboratory Director (LD), documenting that PT samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the PT event. FINDINGS: 1. There no was documentation of LD signature and date of signature on the American Proficiency Institute (API) attestation statements for the 2023 Third Event, 2024 Third Event, and 2025 First Event. 2. It was noted the LD name was handwritten on the API attestation form in the space provided for the LD signature by the TP for the 2023 Third Event. It was also noted the TP name was written in the space provided for the LD signature on the API attestation form for the 2024 Third Event. 3. The CD and TP confirmed the findings on August 13, 2025, at approximately 11:45 A.M.</p>
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish</p>

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 personnel training and competency assessment records, Standard Operating Procedures (SOPs), as well as interview with the CD, the laboratory failed to establish and approve written policies and procedures to assess employee and, if applicable, consultant competency. FINDINGS: 1. There was no documentation of annual Clinical Consultant (CC) and Technical Consultant (TC) competency assessment performance. 2. The current, approved SOPs did not include instructions for performing such activity. 3.. The CD confirmed the findings on August 13, 2025, at approximately 11:30 A.M.

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 lack of PT records as well as interviews with the CD and TP, the laboratory failed to retain, document review, and evaluate PT summary reports. FINDINGS: 1. There was no documentation of PT summary report for the 2023 Second Event. 2. The CD and TP confirmed the findings on August 13, 2025, at approximately 11:45 A.M.

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 on review of the Standard Operating Procedures (SOPs), manufacturer package inserts, lack of thermometer calibration records, as well as interviews with the CD and

TP, the laboratory failed to include requirements for thermometer calibration procedures. FINDINGS: 1. There was no calibration documentation for the Temp Chex Red Spirit Streck thermometer utilized for monitoring the infusion room Frigidaire refrigerator/freezer where API PT samples, Sysmex XN Checks, and patient medications were stored. 2. The thermometer manufacturer's package insert indicated at minimum annual recalibration from date put in use. It was noted that an in-use date of March 30, 2023, was indicated on the manufacturer's package insert. 3. The CD and TP confirmed the findings on August 13, 2025, at approximately 10:35 A. M.

D5429

MAINTENANCE AND FUNCTION CHECKS

CFR(s): 493.1254(a)(1)

(a)(1) Maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.

This STANDARD is not met as evidenced by:

Based on review of the SOPs and manufacturer's specifications, lack of maintenance records, as well as interviews with the CD and TP, the laboratory failed to perform and document analyzer maintenance and function checks with at least the frequency specified by the manufacturer. FINDINGS: 1. There was no documentation of Sysmex XN-530 automated hematology analyzer preventive maintenance or service records provided by the service representative post installation, June 1, 2021. 2. This is contrary to instructions indicated in the current, approved SOPs, Quality Assurance (QA) policies, and manufacturer's specifications. 3. The CD and TP confirmed the findings on August 13, 2025, at approximately 12:00 P.M.

D5439

CALIBRATION AND CALIBRATION VERIFICATION

CFR(s): 493.1255(b)

(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 review of SOPs, manufacturer's specifications, lack of calibration verification records, as well as interview with the TP, the laboratory failed to document analyzer calibration verification. FINDINGS: 1. There was no

	<p>documentation of Sysmex XN-530 automated hematology analyzer calibration verification performance. 2. This is contrary to instructions indicated in the current, approved SOPs, QA policies, and manufacturer's specifications. 3. The TP confirmed the findings on August 13, 2025, at approximately 12:00 P.M.</p>
<p>D5441</p>	<p>CONTROL PROCEDURES CFR(s): 493.1256(a)(b)(c)(g)</p> <p>(a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance.</p> <p>This STANDARD is not met as evidenced by: Based on review of SOPs, lack of analyzer Quality Control (QC) reports and peer review group data records, as well as interview with the TP, the laboratory failed to monitor over time the accuracy and precision of analyzer test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. FINDINGS: 1. There was no documentation of monthly Sysmex XN-530 automated hematology analyzer QC reports and peer review group data records. 2. The TP stated the facility did not perform monthly QC review or peer review group data. 3. This is contrary to instructions indicated in the current, approved SOPs and QA policies. 4. The TP confirmed the findings on August 13, 2025, at approximately 12:00 P.M.</p>
<p>D5791</p>	<p>ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c)</p> <p>(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.</p> <p>This STANDARD is not met as evidenced by: Based on review of SOPs, QA policies, lack of analyzer calibration verification, monthly QC review and peer group review documentation, as well as interview with the TP, the laboratory failed to follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems. FINDINGS: 1. There was no documentation of Sysmex XN-530 automated hematology analyzer calibration verification, monthly QC review, or peer group data review performance. 2. This is contrary to instructions indicated in the current, approved SOPs, manufacturer's specifications, QA policies. 3. The TP confirmed the findings on August 13, 2025, at approximately 12:00 P.M.</p>
<p>D6000</p>	<p>MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403</p>

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 lack of PT records, SOPs, personnel competency assessment records, thermometer calibration documentation, analyzer calibration verification, preventive maintenance, and service records, monthly QC reports and peer review group data records, failure to comply with current, approved SOPs, QA policies, analyzer manufacturer's specifications, as well as interviews with the CD and TP, the LD failed to provide overall management and direction of the laboratory services. Refer to D2014, D5209, D5211, D5403, D5429, D5439, D5441, D5791, and D6020.

D6020

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(5)

(e)(5) Ensure that the quality control and quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur;

This STANDARD is not met as evidenced by:

Based on review of SOPs, QA policies, lack of analyzer calibration verification, monthly QC review and peer group review documentation, as well as interview with the TP, the LD failed to ensure that the QC and QA programs are maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. Refer to D5791.