Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	14D0892372	07/29/2025
Name of Provider or Supplier	**Street Address, City, State**	
Rheumatic Disease Center Physicians Sc	150 N River Rd, Des Plaines, IL	

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. In addition, retain the following: This STANDARD is not met as evidenced by: A Based on review of the laboratory's policy and procedure manual, laboratory Quality Control (QC) records, and interview with technical consultant (TC); the laboratory failed to retain QC records for the Medonic M-series hematology analyzer (Serial number: 48527) for one of five dates reviewed. Findings Include: 1. Review of the laboratory's policy and procedure manual identified the procedure, " Medonic M-series hematology analyzer procedure manual" which stated the following: "QC results obtained from every run must be documented and saved for a minimum of 2 years." 2. Review of laboratory QC records revealed the laboratory failed to maintain any QC records for one of five dates reviewed. Date with no QC records available 12-27-23 3. During the survey on 07/29/2025 at 02:3 pm, the laboratory TC confirmed the laboratory failed to maintain QC results records for the Medonic M-series hematology analyzer for the date of 12-27-23. B Based on review of the laboratory's policy and procedure manual, laboratory Quality Control (QC) records, and interview with technical consultant (TC); the laboratory failed to retain package inserts for QC reagents for the Medonic M-series hematology analyzer (Serial number: 48527) as required for the last two years from the date of survey, 07/29/2025. Findings Include: 1. Review of the laboratory's policy and procedure manual identified the procedure, " Medonic M-series hematology analyzer procedure manual" which stated the following: "The Quality control Package inserts must be saved for a minimum of 2 years." 2. Review of laboratory QC records revealed the laboratory failed to maintain any QC package inserts besides the currently in use package insert for QC reagents

	used for the Medonic M-series hematology analyzer. 3. During the survey on 07/29 /2025 at 02:3 pm, the laboratory TC confirmed the laboratory failed to maintain package inserts for QC reagents for the Medonic M-series hematology analyzer.
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 CMS-209 (Laboratory Personnel Form), laboratory policies and procedures, lack of documentation, and interview with the technical consultant (TC); the laboratory failed to have a competency assessment policy and procedure in place to assess employee competency for one of one TC. Findings include: 1. Review of the CMS-209 (Laboratory Personnel Form) revealed one TC. 2. Review of the laboratory policies and procedures revealed the laboratory lacked a competency assessment policy and procedure to assess the competency of one of one TC. 3. Interview with TC on 7/29/2025, at 12:35 pm, confirmed the laboratory failed to have a competency policy and procedure in place to assess competency for one of one TC.
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 laboratory's policy and procedure manual, laboratory maintenance documents, and interview with the Technical Consultant (TC); the laboratory failed to perform and retain maintenance records for the Medonic M-series hematology analyzer (Serial number: 48527) for five of five dates examined. Findings Include: 1. Review of the laboratory's policy and procedure manual identified the procedure, "Medonic M-series hematology analyzer procedure manual" which stated the following: "Daily cleaning should be performed according to the Medonic M-series user's manual ... All maintenance should be documented (a maintenance log is recommended), and the documentation saved for a minimum of 2 years." 2. Review of laboratory maintenance documents revealed the laboratory failed to have maintenance records for the Medonic M-series Hematology analyzer (Serial number: 48527) for five of five dates reviewed. Dates missing maintenance records 1. 12/27/2023 2. 02/14 /2024 3. 04/19/2024 4. 11/15/2024 5. 03/17/2025 3. During the survey on 07/29/2025 at 02:33 pm, the laboratory TC confirmed the laboratory failed to perform or maintain maintenance records for the Medonic M-series hematology analyzer
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 surveyor review of laboratory policy and procedure manual, lack of documentation, laboratory calibration verification records, and interview with laboratory Technical consultant (TC) ; the laboratory failed to conduct calibration verification for 18 of 18 chemistry/general immunology analytes (albumin, alkaline phosphate, alanine transaminase (ALT), blood urea nitrogen (BUN), calcium, chloride, CO2, complement C3, complement C4, C- reactive protein, creatine kinase, creatinine, glucose, magnesium, potassium, sodium, total bilirubin, total protein, and uric acid) on the Ace Axcel (serial number: 22110573) every six months as required. Findings include: 1. Review of laboratory policy and procedure manual found the procedure titled, "Periodic Calibration, Calibration verifications (AMR) and Assay Correlations" which stated the following: "The AMR must be revalidated at least every six months. If the materials used for calibration or calibration verification include low, midpoint and high values that are near the stated AMR, and if the calibration verification data are within the laboratory's acceptance criteria, the AMR has been verified and no additional procedures are required." 2. No calibration verification documentation for the Ace Axcel was available to surveyors on the date of the survey 07/29/2025 for 18 of 18 chemistry/ general immunology analytes List of analytes with no calibration verification: albumin alkaline phosphate alanine transaminase (ALT) blood urea nitrogen (BUN) calcium, chloride CO2 complement C3 complement C4 C- reactive protein creatine kinase creatinine glucose magnesium potassium sodium total bilirubin total protein uric acid 3. During survey date 07-29-2025 at 02:46 pm, the laboratory TC confirmed the laboratory had failed to perform calibration verification as required for the above mentioned analytes as required every six months.
D6053	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) (b)(9) 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 laboratory personnel report CMS-209, laboratory competency records and interview with the laboratory Technical Consultant (TC); the technical consultant failed to evaluate and document the performance of one of three new TP at

	least semiannually during the first year the individual tests patient specimens. Findings include: 1. Review of laboratory personnel report CMS-209 identified new testing personnel (TP) #2. 2. Review of testing personnel competency records revealed that TP #2 started on 7/8/2024 and had completed a one competency evaluation on 1/15/2025. 3. Interview with the laboratory TC on 07/29/2025 at 12:39 pm confirmed the laboratory failed to perform a second semi-annual competency assessment for TP #2 from 7/8/2024 to 7/8/2025.