Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	01D0300698	03/12/2026
Name of Provider or Supplier	**Street Address, City, State**	
Rheumatology Associates, Pc	12 Office Park Circle, Mountain Brook, AL	

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
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) (d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on a review of the Chemistry calibration records, Chemistry Quality Control (QC) records, Antinuclear Antibodies Patient log, and an interview with the Clinic Coordinator (CC), the Laboratory utilized expired QC reagent and calibration material on the DSX Theratest Chemistry analyzer. The surveyor noted the laboratory utilized expired lots for calibrations and QC for nine weeks out of nine weeks reviewed from January through March 2026. The findings include: 1. A review of the Hematology Calibration and QC records revealed the following: a) Lot #01257044 expired 1-10-2026 for Screen A and Screen B positive controls, b) Lot #01257045 expired 1-10-2026 for Screen A and Screen B Negative controls, c) Lot #01257046 expired 1-10-2026 for Screen A calibrator, d) Lot #01257047 expired 1-10-2026 for Screen B calibrator. e) Dates expired Calibrators and QC performed: 1-13-2026, 1-19-2026, 1-28-2026, 2-4- 2026, 2-9-2026, 2-12-2026, 2-17-2026, 2-25-2026, and 3-4-2026. 2. A further review of the patient log revealed 169 patients were performed during the nine weeks listed above. 3. During the exit interview on 3-12-2026, at 4:32 PM, the CC confirmed the above findings.
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 a review of the Alcor Erythrocyte Sedimentation Rate (ESR) analyzer maintenance records, DSX Theratest Chemistry analyzer maintenance records, Emerald Cell Dyn Hematology analyzer maintenance records, and an interview with the Clinic Coordinator (CC), the Laboratory failed to perform and document maintenance on the Chemistry, Hematology and ESR analyzers as per the manufacturer's requirements. This was noted for the following: a) ESR 4 of 12 months reviewed in 2025, b) DSX 3 of 12 months reviewed in 2025, c) Cell Dyn 2 of 12 months in 2024 and 3 of 12 months reviewed in 2025. The findings include: 1. A review of the maintenance records revealed no documentation of the following: a) ESR Monthly Maintenance April-August 2025, b) DSX Daily and Weekly Maintenance April-July 2025, c) Cell Dyn Daily and Weekly Maintenance September-August 2024 and April-July 2025. 2. During the exit interview on 3-12-2026, at 4:32 PM, the CC confirmed the above findings.
D5437	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(a) (a)Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (a)(1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (a)(2) Using the criteria verified or established by the laboratory as specified in 493.1253(b)(3)-- (a)(2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (a)(2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (a)(3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification. This STANDARD is not met as evidenced by: Based on a review of the Hematology records, and an interview with the Clinic Coordinator, the Laboratory failed to perform calibrations on the Emerald Cell Dyn Hematology analyzer every six months. The laboratory failed to perform one of two calibrations due in 2024. The findings include: 1. A review of the Hematology calibration records revealed the Cell Dyn was calibrated on 9-17-2024 when the new analyzer was validated. There was no documentation of a calibration the first half of 2024 on the old Cell Dyn analyzer. 2. During the exit interview on 3-12-2026, at 4:32 PM, the CC confirmed the above findings.