Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D2296127	09/04/2024
Name of Provider or Supplier	**Street Address, City, State**	
Sarasota Arthritis Center	1945 Versailles Street, Sarasota, FL	

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
D0000	An announced CLIA initial survey was conducted at Sarasota Arthritis Center from 08 /26/24-09/04/24. The laboratory is not in compliance with 42 CFR Part 493, Requirement for Laboratories. The following Conditions were cited: D5400-Analytic Systems
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on observation, interview, review of procedures, and review of manufacturers' instructions, the laboratory failed to establish performance specifications for sensitivity and interfering substances on the modified FDA (Food and Drug Administration) approved Thera Test antinuclear antibody Rheumatoid Factor 3 (RF /3), antinuclear antibody (ANA) Screen, aCL, and Beta 2 GPI (B2GPI) performed from 4/22/2024 to 8/26/2024. (D5423)
D5423	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(2) Each laboratory that modifies an FDA-cleared or approved test system, or introduces a test system not subject to FDA clearance or approval (including methods developed in-house and standardized methods such as text book procedures), or uses a test system in which performance specifications are not provided by the manufacturer

	must, before reporting patient test results, establish for each test system the performance specifications for the following performance characteristics, as applicable: (2)(i) Accuracy. (2)(ii) Precision. (2)(iii) Analytical sensitivity. (2)(iv) Analytical specificity to include interfering substances. (2)(v) Reportable range of test results for the test system. (2)(vi) Reference intervals (normal values). (2)(vii) Any other performance characteristic required for test performance. This STANDARD is not met as evidenced by: Based on observation, interview, review of procedures, and review of manufacturers' instructions, the laboratory failed to establish performance specifications for sensitivity and interfering substances on the modified FDA (Food and Drug Administration) approved Thera Test antinuclear antibody Rheumatoid Factor 3 (RF /3), antinuclear antibody (ANA) Screen, aCL, and Beta 2 GPI (B2GPI) performed from 4/22/2024 to 8/26/2024. Findings included: During a tour of the laboratory on 8 /26/2024 at 10:00 AM the only sample types observed were Serum Separator Tubes (SST). Review of the laboratory procedures and manufacturers' instructions revealed the sample type required was a Red Top for the FDA-approved Thera Test antinuclear antibody for RF/3, ANA Screen, aCL, and B2GPI. Review of the laboratory's Procedure for Implementation of New Test revealed the laboratory did not establish performance specifications for sensitivity and interfering substances. Review of laboratory documents revealed "Trueness and Precision" of the Thera Test antinuclear antibody for RF/3, ANA Screen, aCL, and B2GPI was approved by the Lab Director on 3/5/2024. These documents did not include establishing performance specifications for sensitivity and interfering substances. Review of the CMS 209, Laboratory Personnel Report, signed and dated by the Laboratory Director on 8/26/24 revealed one Testing Person (TP). The TP confirmed on 08/26/2024 at 11:30 AM the Implementation of the Thera Test antinuclear antibody for RF/3, ANA Screen, aCL, and B2GPI approved by the Lab Director on 3/5/2024 and all patient samples from 4 /22/2024 to 8/26/2024 were performed with SST samples.
D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: Based on review of proficiency records, a patient final report, and interview, and the laboratory failed to ensure the test report indicated the appropriate interpretation for antinuclear antibody (ANA) immunology screening results from 4/22/24 to 08/26/24. Findings included: Review of the American Proficiency Institute (API) 2024 First Event documented the Thera Test EL ANA screens (A and B) results were reported and evaluated as qualitative (positive/negative). Review of patient final report #1 revealed the ANA Screen A and B was reported as a quantitative result with numerical results. Interview with the Testing Personnel on 8/26/24 at 1:50 pm

	confirmed the interpretations for the ANA screening results were to be reported as qualitative (positive/negative) not as quantitative with numerical results.