Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0931266	07/23/2026
Name of Provider or Supplier	**Street Address, City, State**	
Arthritis Centers Of Texas	3600 Gaston Ave Suite 100, Dallas, TX	

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 onsite initial survey was conducted on 07/23/2026, and standard level deficiencies were cited.
D5221	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d) All proficiency testing evaluation and verification activities must be documented. This STANDARD is not met as evidenced by: Based on review of Centers for Medicare and Medicaid Services (CMS) 116 form, proficiency testing (PT) 2026 records (1st and 2nd events) and staff interview, the laboratory director failed to attest to the routine integration of proficiency samples into the patient workload for 1 of 2 events in 2026. Findings included: 1. Review of CMS-116 form submitted at time of survey (07/23/2026) revealed the laboratory tested the following unregulated immunology analytes not offered by a PT company: a. EL-aCL b. EL-B2GPI 2. Review of laboratory proficiency testing records in 2026 (Event 1), revealed the following: "Attestation Statement The individual testing or examining samples and the laboratory director must attest to the routine integration of the samples into the laboratory work load using the laboratory's routine methods." Further review of the PT records revealed the laboratory failed to document attestation for routine integration of PT samples into the patient workload, for one of two events in 2026 (Event 1). 3. In an interview on 07/23/2026 at 10:26 AM, the General Supervisor (GS-1) confirmed the laboratory director failed to attest to the routine integration of proficiency samples into the patient workload for 1 of 2 events in 2026. Word Key EL-aCL- Elisa Anticardiotropin EL-B2GPI- Elisa Beta2 Glycoprotein 1
D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a) (a) The laboratory must establish and follow written policies and procedures for each

	of the following, if applicable: (a)(1) Patient preparation. (a)(2) Specimen collection. (a)(3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (a)(4) Specimen storage and preservation. (a)(5) Conditions for specimen transportation. (a)(6) Specimen processing. (a)(7) Specimen acceptability and rejection. (a)(8) Specimen referral. This STANDARD is not met as evidenced by: Based on inspector observation, review of laboratory policy, verification studies, patient final reports, and confirmed in interview, the laboratory failed to ensure acceptable sample stability during transport prior to testing patient samples for 104 of 104 patients randomly reviewed in March and April 2026. Findings included: 1. In a tour of the facility located in Dallas Texas on 07/23/2026 at 09:10 AM, the surveyor observed one DSX Automated Elisa System Analyzer (SN:00032143) available for patient testing. During the tour, the General Supervisor (GS-1) stated patient samples were received from a sister location in Richardson Texas. 2. Review of patient policies, "Antinuclear Antibodies (DSX Automated Elisa System) (Measurements of levels by ELISA)" (approved by the laboratory director on 01/10/2026) revealed the following specimen stability requirements for all ELISA testing: " ...II. Specimen Collection and handing ...Unseparated blood can be stored at 18-25 C for 24 hours before the separation of serum. For separation of the serum, the sample is centrifuged for 10 minutes at 2000 rpm. Serum samples are removed from the clot and placed in a labeled container and refrigerated (2-8 C)." 3. Review of laboratory ELISA verification studies (approved by the laboratory director on 01/10/2026) revealed the laboratory failed to document transport studies of patient specimens from the Richardson location to ensure specimen stability for the above acceptable temperatures. 4. Random review of patient final reports in March and April 2026, revealed the following patient specimens received from the Richardson location for testing: a. March: 50 ELISA patient specimens B. April: 54 ELISA patient specimens 5. In an interview on 07/23/2026 at 10:15 AM, the General Supervisor (GS-1) stated temperatures of samples were not monitored during or after transportation from the Richardson Texas location. This confirmed the laboratory failed to ensure acceptable sample stability during transport prior to testing patient samples for 104 of 104 patients randomly reviewed in March and April 2026. Word Key C- Celsius Rpm- Revolutions per minute
D5801	TEST REPORT CFR(s): 493.1291(a) (a) The laboratory must have an adequate manual or electronic system(s) in place to ensure test results and other patient-specific data are accurately and reliably sent from the point of data entry (whether interfaced or entered manually) to final report destination, in a timely manner. This includes the following: (a)(1) Results reported from calculated data. (a)(2) Results and patient-specific data electronically reported to network or interfaced systems. (a)(3) Manually transcribed or electronically transmitted results and patient-specific information reported directly or upon receipt from outside referral laboratories, satellite or point-of-care testing locations. This STANDARD is not met as evidenced by: Based on review of patient final reports, laboratory information system (LIS), and confirmed in interview, the laboratory failed to document the testing location on patient final reports for 50 of 50 patients randomly reviewed in March 2026. Findings

	included: 1. Random review of patient reports and the laboratory information system in March 2026 revealed the laboratory failed to document the testing address of the facility for 50 of 50 patients tested. 2. In an interview on 07/23/2026 at 11:01 AM, the General Supervisor (GS-1), after review of the above documentation and LIS, confirmed the laboratory failed to document the testing location on patient final reports for 50 of 50 patients randomly reviewed in March 2026.