Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	42D0706461	07/10/2025
Name of Provider or Supplier	**Street Address, City, State**	
Articularis Healthcare Group, Inc	2015 2nd Ave, Summerville, SC	

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 onsite CLIA recertification survey was conducted on June 10. 2025, at the laboratory of Articularis Healthcare Group, Inc by the South Carolina Department of Public Health (SC DPH) Bureau of Nursing Homes and Medical Services. The laboratory was found to be out of compliance with Medicare condition 42 CFR Part 493, CLIA requirements for laboratories. The following is a list of Standard level deficiences cited as a result of the June 10, 2025 CLIA recertification survey:
D2015	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6) (b)(7) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event. This STANDARD is not met as evidenced by: Based on records review, American Proficiency Institute (API) Attestation Statement documents, and staff interview, the laboratory failed to ensure proficiency testing (PT) attestation statements had been signed by the laboratory director (LD) in 2 out of 27 PT events reviewed. Findings included: 1. Review of API PT attestation statements reveals the lack of LD's signature on the following events: a. API 2024 Hematology /Coagulation 3rd event, score 100% b. API 2025 Hematology/Coagulation 1st event, score 100% 2. Review of the API PT attestation statement document reveals the form is to be signed by all testing personnel and the laboratory director. 3. In an interview with the Technical Supervisor (TS) on July 10, 2025 at 1:50pm in the laboratory, the findings were confirmed.
D5291	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(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 general laboratory systems requirements specified at 493.1231 through 493.1236. This STANDARD is not met as evidenced by: Based on records review, lack of documentation, and staff interview, the laboratory failed to document twice annual function checks of the Laboratory Information System (LIS) for results accuracy in 3 out of 3 years reviewed. Findings included: 1. Review of laboratory quality assessment (QA) manual reveals the QA monitors for the laboratory. 2. Twice annual quality assessment of the LIS for functional checks and testing accuracy is not included in the laboratory's QA plan. 3. Review of laboratory records reals a lack of documentation for twice annually quality assessment of the LIS. 4. In an interview with the TS on July 10, 2025, at 1:50pm in the laboratory, the findings were confirmed.
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 direct observation and staff interview, the laboratory failed to ensure that expired testing equipment were not available for use in 4 out of 4 uninterupted power supply units. Findings included: 1. During a tour of the laboratory on July 10, 2025, at 1:50pm, surveyor observed uninterrupted power suppliers (UPS) in use as follows: a. Abbott Alinity c #1analyzer utilizing a POWERVAR UPS with manufacturer recommended battery replacement date of August 2024. b. Abbott Alinity c #2 analyzer utilizing a POWERVAR UPS with manufacturer recommended battery replacement date of March 2023. c. Sysmex XN2000 #1 analyzer utilizing a POWERVAR UPS with manufacturer recommended battery replacement date of April 2024. d. Sysmex XN2000 #2 analyzer utilizing a POWERVAR UPS with manufacturer recommended battery replacement date of May 2024. 2. In a interview with the Technical Supervisor (TS) on July 10, 2025, at 1:50pm in the laboratory, the findings were confirmed.
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 records review and staff interview, the laboratory failed to document the manufacturer's instructions for routine centrifuge maintenance and care for 2 out of 2 centrifuges investigated. Findings included: 1. Review of manufacturer's instruction manual for the LW Scientific ComboXL centrifuge reveals the statement, "Keep the rotor inserts clean". 2. Review of the manufacturer' instruction manual for the LW Scientific MX5 centrifuge reveals the statement, "Keep the rotor shields clean". 3. Review of laboratory maintenance logs reveals a lack of documentation for centrifuge

	maintenance and care. 4. In an interview with Technical Supervisor (TS) on July 10, 2025, at 1:50pm in the laboratory, the findings were confirmed.
D6120	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(7)(8) (b)(7) Identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed; (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. This STANDARD is not met as evidenced by: Based on records review, personnel documentation, and staff interview, the TS failed to ensure evaluation of the competency of all testing personnel at the frequency determined from the laboratory's competency policy and procedure for 1 out of 3 Testing Personnel (TP) reviewed. Findings included: 1. Review of the laboratory procedure manual reveals the "Competency Testing Procedure" which indicates competency assessment are to occur as follows: a. Initial Competency b. 6 Months Competency c. Annual Competency 2. Review of personnel records reveals a lack of documentation for 6 months competency evaluation for TP3. 3. In an interview with the TS on July 10, 2025, at 1:50pm in the laboratory, the findings were confirmed.