Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 11D0675261	**(X3) Date Survey Completed** 01/07/2025
Name of Provider or Supplier Athens Heart Center, Pc	**Street Address, City, State** 11973 Augusta Road, Lavonia, GA	
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	A Clinical Laboratory Improvement Amendments (CLIA) recertification survey was completed on January 7, 2025. The laboratory was not in compliance with applicable CLIA requirements found at 42 CFR 493.1 through 42 CFR 493.1780. The following deficiencies were cited:
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods. This STANDARD is not met as evidenced by: Based on proficiency test (PT) documents review and staff interview, the laboratory director failed to attest that (PT) samples were ran in the same manner as patient samples by not signing attestation documents in a timely manner in 2023 and 2024. Findings: 1. American Proficiency Institute (API) (PT) documents review revealed the laboratory director (LD) failed to sign attestation statements, confirming that PT samples were integrated into the daily sample processing workflow in a timely manner as follows: Chemistry event 1 2023 - results submitted 1/31/2023, LD signed 8 /13/2023 - 7 months later. Hematology event 2 2023 - results submitted 3/29/23, LD signed 8/13/2023 - 5 months later. Chemistry event 2 2023 - results submitted 6/5 /2023, LD signed 6/28/2024 - 12 months later. Immunology event 2 2023 - results submittes 8/15/2023, LD signed 6/28/2024 - 10 months later. Chemistry event 3 2023 - results submitted 8/28/2023, LD signed 6/28/2024 - 8 months later. Hematology event 3 2023 - results submitted 11/9/2023, LD signed 6/28/2024 - 7 months later. Chemistry event 1 2024 - results submitted 1/19/2024, LD signed 6/29/2024 - 5 months later. Hematology event 3 2024 - results submitted 11/12/2024, LD signed 12

	/6/2024 - 3 weeks later. 2. An interview with the laboratory manager (TP #3 CMS 209) in the review room at approximately 1:30 PM on 01/07/2025 confirmed the above findings.
D5211	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a) The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part. This STANDARD is not met as evidenced by: Based on proficiency test (PT) documents review and staff interview, the laboratory director failed to review and evaluate proficiency testing (PT) results of the American Proficiency Institute (API) by not signing (PT) Evaluation documents in a timely manner in 2023 and 2024. Findings: 1. American Proficiency Institute (API) (PT) documents review revealed the laboratory director failed to review and sign (PT) results evaluation statements in a timely mannar for the following (PT) events: 2023 - Events #1 Hematology evaluation forms were signed 8/13/2025 (4 months later). There were no signatures for the remaining evaluation forms for Events #2 and #3 for Chemistry, Immunology and Hematology in 2023. 2. The American Proficiency Institute (API) (PT) events #1, #2 and #3 for Chemistry, Immunology and Hematology had no review signatures in 2024. 4. An interview with the laboratory manager (TP #3 CMS 209) in the review room at approximately 1:45 PM on 01/07 /2025 confirmed the above findings.
D6005	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(c) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (c) The laboratory director must be accessible to the laboratory to provide onsite, telephone or electronic consultation as needed. This STANDARD is not met as evidenced by: Based on (PT) documents review and interview with the laboratory manager, the Laboratory director failed to ensure that ALL Quality Assurance (QA) guidelines were followed to identify and fix problems in the laboratory in 2023 and 2024 as required by Clinical Laboratory Improvement Amendments (CLIA). Findings: 1. American Proficiency Institute (API) and Quality Assurance (QA) documents review revealed the lab director, who is also the technical consultant (TC) , did NOT review and sign-off on (PT) attestation and evaluation documents in a timely manner from 2023 -2024. 2. An interview with the laboratory manager in the review room on 01/07 /2025 at approximately 12:35 PM, confirmed the laboratory director failed to ensure proper oversight of the laboratory's (QA) activities in 2023 and 2024.