Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	11D1045979	05/17/2023
Name of Provider or Supplier	**Street Address, City, State**	
Stevens Health Services	201 East 16th Avenue, Cordele, 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 recertification survey was performed on May 17, 2023. The facility was found to be NOT in compliance with the CLIA conditions and standards for specialties /subspecialties for 42 CFR. D5200: (Condition) General Laboratory Systems 493.1230 D6000: (Condition) Moderate Complexity Laboratory Director 493.1403 NOTE: The CMS-2567 (Statement of Deficiencies) is an official , legal document,. All information must remain unchanged except for entering the Plan Of Correction (POC), correction dates, and the signature space. Any discrepancy n the original deficiency citation(s) will be reported the the Georgia Regional Office (RO) for referral the Office of the Inspector General (OIG) for possible fraud if the information is inadvertently changed by the provide/supplier, the State Survey Agency (SA) should be notified immediately.
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 review of the American Proficiency Institute (API) Proficiency Testing (PT) documents for 2021, 2022, and 2023, and staff interview, the laboratory failed to provide signed Attestation Statements, verifying the PT testing samples were handled in the same manner of patient samples. Findings: 1. API PT testing for year 2021, the laboratory failed to provide a signed Attestation Statement form for the following: Hematology Specialty, 3rd event - the laboratory failed to provide a signed Attestation statement. Chemistry, Core Specialty, 3rd event - the laboratory failed to provide a signed Attestation statement Microbiology, Specialty , 3rd event - the laboratory failed to provide a signed attestation statement API PT testing for year 2022, the laboratory failed to provide a signed Attestation Statement for the following:

	Hematology Specialty, 1st, 2nd, and 3rd event- the laboratory failed to provide a signed Attestation Statement Chemistry, Core Specialty, 1st, 2nd,and 3rd event- the laboratory failed to provide a signed Attestation Statement Microbiology Specialty, 1st, 2nd, and 3rd events- the laboratory failed to provide a signed Attestation Statement API PT testing for year 2023, the laboratory failed to provide a signed Attestation Statement for the following: Hematology Specialty, 1st and 2nd event- the laboratory failed to provide a signed attestation Statement Chemistry Core Specialty, 1st event - the laboratory failed to provide a signed attestation statement Microbiology Specialty, 1st event- the laboratory failed to provide a signed attestation statement 2. Interview with the Technical Consultant, (TC), on May 17, 2023 at approximately 11: 21 am, in the conference room confirmed the aforementioned Statements.
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. This STANDARD is not met as evidenced by: Based on failure to retain documentation for Quality Control (QC) records for the Specialty Hematology, and staff interview, the laboratory failed to show documentation from December 2021 to December 2022 demonstrating QC had been performed. Findings: 1. Review of the maintenance logs for the Sysmex 300 for December 2021 to December 2022, confirmed that QC was performed on the Sysmex, as marked on the monthly logs, there were no instrument print outs to verify. The Technical Consultant confirmed that he had reviewed the QC on the instrument however the instrument archives no more than two months of data. The QC documents were not printed from the analyzer. 2. Interview with the TC, on May 17, 2023 at approximately 12:10 pm in the conference room confirmed the above aforementioned statement.
D5200	GENERAL LABORATORY SYSTEMS CFR(s): 493.1230 Each laboratory that performs nonwaived testing must meet the applicable general laboratory systems requirements in 493.1231 through 493.1236, 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 general laboratory systems and correct identified problems specified in 493.1239 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on the laboratory not having any Quality Assurance (QA) documents from December 2021 through April 2023, the laboratory did not monitor or evaluate the overall quality of the general laboratory systems and had not corrected identified problems for each specialty and subspecialty of testing performed. REFERENCE D5293
D5293	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(b)(c)

	(b) The general laboratory systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of general laboratory systems quality assessment reviews with appropriate staff. (c) The laboratory must document all general laboratory systems quality assessment activities. This STANDARD is not met as evidenced by: Based on review of the Quality Assessment (QA) documents, and staff interview, the laboratory failed to perform QA checks from December 2021 through April 2023. Findings: 1. Review of the QA documents, or the lack there of, the laboratory failed to have documentation from December 2021 through April 2023 indicating that a review of the effectiveness of corrective actions had been taken to resolve problems, revision of policies or procedures necessary to prevent recurrence of problems, or a discussion of general laboratory systems quality assessment reviews, with appropriate staff, had occured. 2. Interview with the current TC, on May 17, 2023, at approximately 12 pm, in the conference room, confirmed the aforementioned statement.
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: Based on review of the Training and Competency documents for the Testing Personnel (TP), the Laboratory Director failed to provide overall management and direction of the laboratory TP staff for moderate complexity testing. Findings: The testing personnel hired in May 2022, did not have initial training or 6 month competency assessment REFERENCE: D6029
D6029	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(11) 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. (e) The laboratory director must-- (e)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results. This STANDARD is not met as evidenced by: Based on review of Testing Personnel and confirmed by staff interview, the Laboratory Director failed to provide initial training documents and 6 month competency documents for TP-1 and TP-2 listed on the Centers for Medicare and Medicaid Services (CMS) form Testing Personnel form (209). Findings: 1. Review of testing personnel TP-1 and TP-2 documentation confirmed that there was no

	documented initial training documents for TP-1 or TP-2. There were no documented 6 month competency documents for either TP-1 or TP-2. The new Technical Consultant, (TC) hired October 2022, performed a competency assessment on TP-1 and TP-2 on 4/3/2023. 2. Interview with the new TC, on May 17, 2023, at approximately 11:30 am, in the conference , confirmed the above aforementioned statements.