Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	11D1045979	07/18/2025
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 Clinical Laboratory Improvement Amendments (CLIA) Recertification Survey was completed on July 18, 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:
D3011	FACILITIES CFR(s): 493.1101(d) Safety procedures must be established, accessible, and observed to ensure protection from physical, chemical, biochemical, and electrical hazards, and biohazardous materials. This STANDARD is not met as evidenced by: A tour of the laboratory confirmed that there was not adequate protection against all potential hazards. THE FINDINGS INCLUDE: 1. A tour of the laboratory testing area revealed that a designated clean sink, to protect against potential cross contamination of specimens and testing personnel, was not available in the testing laboratory. 2. A tour of the laboratory facility revealed that 2 out of 2 of the fire extinguishers had no evidence of inspections, to assure functionality. 3. An interview with the laboratory staff confirmed that personnel were not informed of the location of all fire extinguishers in the testing laboratory facility. 4. An interview with the laboratory staff confirmed that personnel had not been trained on the proper usage of the fire extinguishers. 5. An exit interview, with the TC, on July 18, 2025, at 2:00 pm confirmed the lack of adequate protection against all potential hazards in the testing laboratory.
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: A review of 2023 - 2025 Maintenance Records, 2023- 2025 Temperature Records, and 2023 - 2025 Quality Control Records confirmed that the laboratory failed to perform routine monitoring of laboratory operations to assure quality testing. THE FINDINGS INCLUDE: 1. A review of 2023 - 2025 Maintenance Records, 2023-2025 Temperature Records, and 2023 - 2025 Quality Control Records confirmed that there was no documentation of quality assurance procedures 2. An exit interview, with the TC, on July 18, 2025 at 2:00 pm confirmed that the laboratory failed to perform routine monitoring of laboratory operations to assure quality testing.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) (b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (b)(1) Water quality. (b)(2) Temperature. (b)(3) Humidity. (b)(4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: A tour of the reagent storage refrigerator, the reagent storage freezer, and the 2023 - 2025 Temperature Records, confirmed that storage requirements, set by the manufacturer, was not met. THE FINDINGS INCLUDE: 1. A review of the reagents stored in the reagent storage freezer revealed the following manufacturers set storage requirements: a. TRIAGE 5 CONTROL 1: Storage requirement of ?-20C (?-4F); b. BRT LIQUID ASSAYED CHEMISTRY + LIPID CONTROL: Storage requirement of ?-15C (?5F); c. ACCESS FREE T4 CALIBRATORS: Storage requirement of ?-20 C (?-4F); d. ACCESS FREE T4 CALIBRATORS: Storage requirement of ?-20C (?-4 F); e. BIORAD LIQUICHEK IMMUNOLOGY PLUS CONTROLS Storage requirement of -70C - -20C (-94 F - -4F); f. QUIDEL TRIAGE TOX DRUG SCREEN TEST KIT Storage requirement of 2C - 8C (35.6F - 46.4 F) was stored in the freezer; and g. THAWED BECKMAN ACCESS CALIBRATOR: Storage requirement of ?-20C (UNTHAWED) and 8C (THAWED) (-4F - 46.4F); 2. A review of the thermometer used to monitor the temperature of the freezer revealed the current temperature of 14.56F (-9.69C). 3. A review of the 2024 - 2025 Temperature Records log sheet revealed an acceptable range of -22C - -8C (-8F - 18F) for the Reagent Storage Freezer. The Reagent Storage Freezer thermometer displayed a minimum setting of -5.15F (-20.5C) and a maximum setting of 43.98F (6.7 C). 4. A review of the 2024 - 2025 Temperature Records revealed there were no refrigerator temperatures recorded for the month of January 2024 and for April 22 - 30, 2024. There were also no freezer temperatures recorded for April 22 - 30, 2024. 5. A review of Temperature Records revealed that the required storage temperature of ?-20C (?-4 F) was met only on 13 of 547 days of storage usage. 6. A review of the 2024 - 2025 Temperature logs revealed that quality assurance overview and corrective action

	documentation was not performed. 7. An exit interview, with the TC, on July 18, 2025, at 2:00 pm confirmed the failures of temperature and storage requirements.
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: A tour of the facility revealed that expired reagents were stored in the Reagent Storage Freezer for patient testing and reult reporting. THE FINDINGS INCLUDE: 1. A review of the reagents, stored in the Reagent Storage Freezer, revealed the use of the following expired reagents: a. AUDIT BILIRUBIN SUPPLEMENT LINEARITY REAGENTS expired 06/09/2023 b. AUDIT GENERAL CHEMISTY LINEARITY REAGENT expired 05/13/2023 2. An exit interview, with the TC, on July 18, 2025 at 2:00 pm confirmed these findings of expired reagents.
D6020	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) (e)(5) Ensure that the quality control and quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur; This STANDARD is not met as evidenced by: A review of 2023 - 2025 Maintenance Records, 2023- 2025 Temperature Records, and 2023 - 2025 Quality Control Records confirmed that the Laboratory Director failed to ensure that quality control and quality assessment programs were maintained to assure the quality of the laboratory services. Refer to D5291, D5413, and D5417
D6084	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(2) provide a safe environment in which employees are protected from physical, chemical, and biological hazards; This STANDARD is not met as evidenced by: A review of 2023 - 2025 Maintenance Records, 2023- 2025 Temperature Records, and 2023 - 2025 Quality Control Records confirmed that the Laboratory Director failed to provide a safe environment for the laboratory testing personnel. Refer to D3011