Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	11D1045979	08/08/2019
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	An initial Clinical Laboratory Improvement Amendments (CLIA) survey was completed on August 8, 2019. The laboratory was not in compliance with all 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: Tour of the laboratory and staff interview, showed that the laboratory did not have sterile solutions in the eyewash bottles, hanging on the wall. Findings: 1. During a tour of the laboratory, it was observed that the eyewash station bottles were empty and did not have sterile solution in either of the two bottles. It was also observed that the eyewash station bottle set was not attached to the wall properly and would fall off the wall if they were touched. 2. Interview with the Laboratory Director and Technical Consultant, on August 8, 2019, at approximately 12:50 pm in the conference room confirmed that the eyewash station bottle set was empty.
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 review of the Laboratory operating manuals, and staff interview, the laboratory did not have written Quality Assurance policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the general laboratory systems requirements. Findings: 1. Review of the operating manuals showed that there was not a Quality Assurance policy and procedure for an ongoing mechanism to monitor, assess, and correct problems in the general laboratory system. 2. Staff interview with the Laboratory Director and Technical Consultant, on August 8, 2019, at approximately 12:53pm in the conference room, confirmed that the laboratory did not have a Quality Assurance Policy and Procedure.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on review of the Standard Operating Procedures (SOP) for the testing performed in the laboratory and staff interview with the Laboratory Director (LD), and the Technical Consultant (TC), the laboratory failed to provide procedures that covered all aspects of the test being performed in Chemistry, Hematology, and Immunology. Findings: 1. Review of the SOP for testing performed in Hematology, Chemistry, and Immunology, the procedures did not include all aspects of the testing procedure, pre-analytical, analytical, post analytical, and reporting. 2. Staff interview with the LD, and the TC, on 08/08/2019, at approximately 1245 pm in the conference room, confirmed that the laboratory did not have SOPs for the testing performed in Chemistry, Hematology, and Immunology that included pre-analytical, analytical, post-analytical and reporting aspects of testing.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(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: (1) Water quality. (2) Temperature. (3) Humidity. (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: During a tour of the laboratory, review of the temperature charts, and staff interview, the laboratory did not have a thermometer in the freezer. Findings: 1. During a tour of the laboratory, it was observed that there was not a thermometer in the freezer. 2. Interview with testing personnel (CMS209), on August 8, 2019, in the laboratory at approximately 11:30am, confirmed that there was not a thermometer in the freezer. The thermometer that was in the freezer was packed up on July 10, 2019, and shipped back to the contracted reference lab. 3. Review of the the temperature charts for the freezer, it was determined that freezer temperatures were being recorded on the temp log without a thermometer after July 10, 2019. There was not a temperature chart for August, 2019. 4. Interview with the Laboratory Director and the Technical Consultant, on August 8, 2019, at approximately 12:35pm, in the conference room, confirmed that there was not a thermometer in the freezer. Temperatures were recorded after the thermometer was removed from the freezer and sent back to the contracted reference lab. Also confirmed, there were not temperature charts for August 2019.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on review of the Implementation documents for the Easy RA Chemistry Analyzer (Easy RA) for urine drugs of abuse, and staff interview the Laboratory Director(LD) failed to sign off the acceptance of the Implementation Documents. Findings: 1. Review of the implementation documents for the Easy RA confirmed that the LD had not signed the documents, as required, prior to testing initiation. 2. Interview with the LD, on August 8, 2019, at approximately 12:40 pm, in the conference room, confirmed that the LD had not signed the implementation documents as required prior test initiation.
D6032	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(14) 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)(14) Specify, in writing, the responsibilities and duties of each consultant and each person, engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or results reporting, and whether consultant or director review is required prior to reporting patient test results. This STANDARD is not met as evidenced by: Based on review of the staff Job Descriptions, and staff interview, the Laboratory Director (LD) failed to get signed copies of the staff Job Descriptions for the testing personnel and Technical Consultant. Findings: 1. Review of the job descriptions, for the laboratory staff, confimed that the staff had not signed individual job descriptions as related to their job requirements. 2. Staff interview with the LD, on August 8, 2019, at approximately 12:55 pm in the conference room, confirmed that the laboratory staff had not signed a copy of their job description.
D6046	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8) (b) The technical consultant is responsible for-- (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 review of testing personnel (TP) training records, and staff interview, the Technical Consultant (TC) did not provide documentation that the TP's had initial traiing. Findings: 1. Review of the TP training records, there was not documentation of initial training for either TP listed on the CMS 209 form. 2. Interview with the TC, on August 8, 2019, at approximately 12:30 pm, in the conference room, confirmed that the initial training was not documented as being performed.
D6065	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(b)(1)(2)(3)(4)(i) (b) Meet one of the following requirements: (b)(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located or have earned a doctoral, master's, or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; or (b)(2) Have earned an associate degree in a chemical, physical or biological science or medical laboratory technology from an accredited institution; or (b)(3) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(4)(i) Have earned a high school diploma or equivalent; and This STANDARD is not met as evidenced by: Based on review of the testing personnel records, and staff interview with the Laboratory Director (LD), and Technical Consultant (TC), the laboratory failed to provide educational documents to qualify the testing personnel. Findings: 1. Review

	of the testing personnel records did not include a copy of the education requirements for high school diploma, or equivalent. 2. Staff interview with the LD, and TC on August 8, 2019, at approximately 12:40 pm , in the conference room, confirmed that copies of the testing personnel's high school diploma, or equivalent, were not available.