Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	11D1045979	07/28/2021
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 28, 2021. Condition and Standard level Citations were found. 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:
D2000	ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801 Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994. This CONDITION is not met as evidenced by: Based on review of the 2020, American Proficiency Institute (API) Proficiency Testing (PT) documents and the 2020 Order Confirmation, the laboratory failed to register for PT. The order confirmation states that the PT was ordered on June 11, 2020. The laboratory missed the first event for Hematology and the first and second event for Chemistry, there was no evidence supporting attempts to order off schedule events to cover the missed events. REFERENCE: D2089, D2123, D2096
D2089	ROUTINE CHEMISTRY CFR(s): 493.841(c) Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories

	failing to participate in a testing event only if-- (1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results; (2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and (3)The laboratory participated in the previous two proficiency testing events. This STANDARD is not met as evidenced by: Based on review of the American Proficiency Institute (API) Proficiency Testing (PT), documents, the 2020 Order Confirmation, and Staff Interview, the laboratory failed to participate in the speciality of Chemistry for events 1 and 2 of 2020. Findings: 1. API PT document review and 2020 Order Confirmation confirmed the laboratory had not ordered the 2020 PT samples until June 11, 2020. The 1rst and 2nd events for the Chemistry speciality were missed. The laboratory did not participate in the 1rst or 2nd event for the Chemistry speciality and there was no documentation that the laboratory ordered off schedule samples for the missed events. 2. Interview with the TC, on July 28, 2021, at approximately 2:16 pm in the upstairs conference room confirmed the aforementioned statement
D2096	ROUTINE CHEMISTRY CFR(s): 493.841(f) Failure to achieve satisfactory performance for the same analyte or test in two consecutive testing events or two out of three consecutive testing events is unsuccessful performance. This STANDARD is not met as evidenced by: Based on review of the American Proficiency Institute (API), Proficiency Testing (PT) documents, and staff interview, the laboratory failed to score acceptable results in two consecutive events for the speciality Chemistry in 2020. The laboratory failed to order the API, PT documents in time to complete events 1 and 2. There was no documentation that the laboratory ordered off schedule samples for the missed events. Findings: 1. Review of the APT PT documents confirmed the laboratory failed to score acceptable results in two consecutive events (events 1 and 2) in 2020, the for specialty Chemistry. The following subspecialty test did not receive acceptable scores: 0255-ALT/SGPT 0265-ALBUMIN 0275-ALK PHOS 0295-AST/SGOT 0305-BILI,TOTAL unsuccessful in three out of five events -2020, events one and two and 2021 event 2 score of 40% 0345-CALCIUM, TOTAL 0355-CHLORIDE 0365-CHOLESTEROL, TOTAL unsuccessful in 4 events-2020, events one, two, and three, and 2020 events 1 and 2 0375-CHOLESTEROL,HDL unsuccessful in 4 events-2020, events one, two, and three, and 2020 events 1 and 2 0385- CK, TOTAL 0395-CK, ISO 0405-CREATININE 0415-GLUCOSE(NON-WAIVED) unsuccessful in three out of five events-2020, events one and two, and 2021 event 2 score of 40% 0425-IRON, TOTAL 0455-MAGNESIUM 0465-POTASSIUM 0475-SODIUM 0485-TOTAL PROTEIN 0495-TRIGLYCERIDE 0505-BLOOD UREA NITROGEN 0545-FREE THYROXIN 0585-THYROID STIMULATING HORMONE 2. Staff interview with the TC, on July 28, 2021, at approximately 2:10 pm, confirmed the above aforementioned statement. \
D2123	HEMATOLOGY

	CFR(s): 493.851(c) Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if-- (1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results; (2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and (3) The laboratory participated in the previous two proficiency testing events. This STANDARD is not met as evidenced by: Based on review of the American Proficiency Institute (API) Proficiency Testing (PT), documents, the 2020 Order Confirmation, and Staff Interview, the laboratory failed to participate in the speciality Hematology event 1 of 2020. Findings: 1. API PT document review and 2020 Order Confirmation, showed that the laboratory had not ordered the 2020 PT samples until June 11, 2020. The first event for the speciality Hematology were missed. The laboratory did not participate in the 1rst event for the specialty Hematology and there was no documentation that the laboratory ordered off schedule samples for the missed events. 2. Interview with the TC, on July 28, 2021, at approximately 2:15 pm, in the upstairs conference room, confirmed the 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 review of the Calibration and Quality Control documents for the Hematology Analyzer, (Sysmex) XP-300 for 2019 and 2020, and review of the Calibration / Verification and Quality Control documents for the Medica (EASYRA) for 2019 and 2020, the Laboratory failed to monitor and evaluate the overall quality of the general laboratory systems for each speciality and subspecialty of testing performed. REFERENCE: D5439, D5447, D5211, D5211
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 review of the American Proficiency Institute (API), Proficiency Testing

	(PT), documents and staff interview, the laboratory failed to document that the all PT evaluation reports were signed as reviewed by the Laboratory Director (LD) or the Technical Consultant (TC) for 2019, 2020, and 2021. Findings: 1. Review of the API, PT documents for 2019, 2020, and 2021, the laboratory failed to document review of the following events: 2019, Chemistry Core, event 3 2020, Hematology, event 3 2020, Chemistry Core, event 3 2021, Chemistry Core, event 2 2. Staff interview with the TC, on July 28, 2021, at approximately 2:15 pm, in the upstairs conference room, confirmed the above aforementioned statement.
D5221	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d) All proficiency testing evaluation and verification activities must be documented. This STANDARD is not met as evidenced by: Based on review of the American Proficiency Institute (API) Proficiency Testing (PT) documents for 2019, 2020, and 2021, and staff interview, the laboratory failed to document corrective action for scores of less than 100%. Findings: 1. Review of the APT, PT documents, the laboratory failed to document corrective action for scoring less than 100% for the following scores: 2019- Hematology event 3 for a score of 40% for Mean Corpuscular Hemoglobin (MCH), and Red cell Distribution Weight (RDW) Chemistry event 1 for a score of 20% for Creatine Kinase (CK), and 80% for CK isoenzyme Chemistry event 3 for a score of 0% for Total Protein, and 67% for Prostate Specific Antigen 2020- Hematology event 2 for a score of 80% for White Blood Cell Count, and Neutrophils Chemistry event 3 for a score of 80% for Total Bilirubin 2021- An off schedule Chemistry event was submitted Jun 2021, with scores Total Bilirubin 40%, Cholesterol 80%, Ferritin 0%, Folate 0%, Glucose, 40%, Sodium 80%, Total Iron Binding Capacity 80%, Vitamin B-12 0%, Prostate Specific Antigen, 0% Testosterone 0% 2. Staff interview with the Technical Consultant on July 28, 2021, at approximately 2:25 pm in the upstairs conference room, confirmed the above aforementioned statements.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for

	verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: Based on review of the Calibration / Verification documents for the (Sysmex) XP-300, hematology analyzer for 2019 and 2020, the laboratory failed to document calibration from March 2019 to February 2020, and for the Chemistry Analyzer (EasyRA), the laboratory failed to document Calibration Verification from February 2020 to February 2021. Findings: 1. Review of the Calibration documents for the Sysmex, the laboratory failed to provide documentation that a Calibration was performed on the Sysmex every 6 months. The laboratory had no documentation of calibration performed on March 2019, February 2020, August 2020, and February 2021. 2. Review of the Calibration verification documents for the Medica EasyRA, the laboratory failed to provide documentation that a Calibration/Verification was not performed on the EasyRA every 6 months. The laboratory had documentation for a calibration/verification on February 2020, and on February 2021. 3. Staff interview with the TC on July 28, 2021 at approximately 2:30 pm in the upstairs conference room, confirmed the above aforementioned statements.
D5447	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(i)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each quantitative procedure, include two control materials of different concentrations; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of the Quality Control (QC) documents for the Sysmex XP-300, Hematology analyzer, and the Medica, EasyRA, Chemistry analyzer, for years 2020 and 2021, and staff interview, the laboratory failed to provide documents of daily QC performance. Findings: 1. Review of the QC documents for the Sysmex, confirmed the that the laboratory failed to perform QC was from March thru December 2020. 2. Review of the QC documents for the EasyRA confirmed that the laboratory failed to have documentation supporting that QC was performed from February 2020 thru February 2021. 3. Interview with the TC, on July 28, 2021, at approximately 2:25pm, in the upstairs conference room, confirmed the above aforementioned statements.
D6015	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4) 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)(4) Ensure that the laboratory is enrolled in an HHS approved proficiency testing program for the testing performed. This STANDARD is not met as evidenced by:

	Based on review of the American Proficiency Institute (API) Proficiency Testing (PT) document 2020 Order Confirmation, the Laboratory Director failed to ensure the laboratory was enrolled in an HHS approved proficiency testing program for all testing performed in the laboratory. Document review confirms the delayed PT enrollment on June 11, 2020. Findings: 1. Review of the 2020 API order confirmation, confirmed that PT enrollment did not occur until June 11, 2020 for all testing perfomed in the laboratory. 2. Staff interview with the Technical Consultant on July 28, 2021, at approximately 2:20, confirmed the above aforementioned statement.