Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	11D0021371	06/12/2025
Name of Provider or Supplier	**Street Address, City, State**	
Screven County Hospital, Llc	215 Mims Road, Sylvania, 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 June 12, 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:
D2016	SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c) (a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history. This CONDITION is not met as evidenced by: A review of 2023 - 2025 API Proficiency Testing Records confirmed that the Laboratory failed to investigate and perform corrective actions for unsuccessful proficiency test scores. THE FINDINGS INCLUDE: 1. A review of the 2023 - 2025 API Proficiency Testing Records confirmed: 2023 Chemistry Event 2 scored 80% for

	the HDL analyte; 2023 Chemistry Event 3 scored 80% for ALT, ALB, ALK, AMY, AST, CA, CL, CHOL, HDL, CREA, LDH, TP, TRIG and a 60% score for TBIL 2024 Chemistry Event 1 scored 80% for PCO2 2024 Chemistry Event 2 scored 80% for PO2 2025 Chemistry Event 1 scored 80% for Hgb- A1C. 2. A review of the Hematology proficiency testing records for 2023 - 2024 revealed: 2023 Hematology Event 2 score of 60% for PT 2024 Hematology Event 2 score of 80% for WBC 2024 Hematology Event 3 score of 80% for WBC, 20% score for PT and a 40% score for PTT 2025 Hematology Event 1 revealed a score of 88% for WBC DIFF 3. A review of the Toxicology proficiency testing records for 2023 - 2024 revealed: 2023 Toxicology Event 3 score of 80% for VALP 2025 Toxicology Event 1 score of 80% for ALC and a 60% score for VANCO. 4. A review of the Endocrinology proficiency testing records for 2023 - 2024 revealed: 2024 Endocrinology Event 1 score of 80% for T4 2024 Endocrinology Event 2 score of 80% for T4 2024 Endocrinology Event 3 80% score for T4, T3, and T4. 5. A review of the Immunohematology proficiency testing records for 2023 - 2024 revealed: 2023 Immunohematology Event score of 80% for Compatibility Testing 2024 Immunohematology Event 1 score of 20% for Antibody Detection 2024 Immunohematology Event 3 score of 80% for Antibody Detection Testing. 6. A review of 2023 - 2025 Proficiency Testing Records confirmed that documentation of investigation/corrective actions were not taken for the unsuccessful scores. 7. An exit interview with the Laboratory Team, on June 12, 2025, at 4:30pm, confirmed that the Laboratory failed to investigate or perform corrective actions for unsuccessful proficiency testing results.
D2128	HEMATOLOGY CFR(s): 493.851(e) (e)(1) For any unsatisfactory analyte or test performance or testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure. (2) For any unacceptable analyte or testing event score, remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event. This STANDARD is not met as evidenced by: A review of 2023 - 2025 API Proficiency Testing Records confirmed that the laboratory failed to take or document remedial actions for 2 out of 5 unsuccessful Prothrombin (PT) analyte scores. THE FINDINGS INCLUDE: 1. A review of 2023 - 2025 API Hematology Proficiency Testing Records revealed an unsuccesful score of 60% for PT in 2023 Hematology Event 2 and an unsussessful score of 20% for PT in 2024 Hematology Event 3. 2. A review of 2023 - 2025 API Hematology Proficiency Testing Records confirmed 2 out of 5 unsuccessful scores for PT. 3. A review of 2023 - 2025 Proficiency Testing Records confirmed that documentation of remedial action was not taken for the unsuccessful scores. 4. An exit interview, with the Lab Team, on June 12, 2025, at 4:30pm confirmed that the Laboratory failed to document remedial actions for 2 out of 5 unacceptable PT analyte scores.
D2160	ABO GROUP AND D(RHO) TYPING CFR(s): 493.859(e) (e)(1) For any unsatisfactory testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the

	technical assistance necessary to correct problems associated with a proficiency testing failure. (2) For any unacceptable analyte or unsatisfactory testing event score, remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event. This STANDARD is not met as evidenced by: A review of 2023 - 2025 API Proficiency Testing Records confirmed that the Laboratory failed to take remedial actions for 2 out of 5 unacceptable analyte scores for Compatibility Testing and Antibody Detection Testing. THE FINDINGS INCLUDE: 1. A review of 2023 - 2025 API Proficiency Immunohematology Testing Records confirmed scores of 80% in 2023 Immunohematology Profiency Testing performance. 2. A review of 2023 - 2025 API Proficiency Immunohematology Testing Records confirmed scores of 80% in both the 2024 Immunohematology Event 1 and 2024 Immunohematology Event 3 for Antibody Detection Testing. 3. A review of 2023 - 2025 Proficiency Testing Records revealed that there was no documentation of remedial actions for the failed scores. 4. An exit interview with the Lab Team on June 12, 2025, at 4:30pm confirmed that the Laboratory failed to take remedial actions for unacceptable analyte scores.
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, 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 analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: A review of 2023 - 2025 Quality Control Records, 2023 - 2025 Blood Bank Records, 2023 - 2025 Personnel Records, 2023 - 2025 API Proficiency Testing Records, and current Laboratory Procedure Manual confirmed that the laboratory failed to monitor, evaluate, and correct identified problems for each specialty and subspeciality. THE FINDINGS INCLUDE: 1. A review of the 2023 - 2025 Hematology Quality Control Records revealed in the month of June 2024, the Coulter Latron CP-X controls had ten (10) repeated high end QC failures without investigative assessment or corrective actions. 2. A review of the aforementioned 2023 - 2025 analytical laboratory records revealed that quality assurance oversight performance and/ or documentation of the laboratory Analytical System did not occur. 3. A review of the 2023 - 2025 Personnel Records revealed a Letter of Delegation of duties by LD to the TS (See Form 209: Personnel Report) however contained no effective date. 4. An additional Letter of Delegation found in the 2023 - 2025 Personnel Records revealed the delegation of operation oversight to an unidentified Respiratory Supervisor. The qualification could not be verified and was also without an effective date. 5. An exit interview with the Lab Team, on June 12, 2025, at 4:30pm confirmed the laboratory failed to monitor, evaluate, or identify problems for each specialty, subspeciality, or personnel in the laboratory.
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 review of 2023 - 2025 Temperature Records confirmed that the Laboratory failed to assure the appropriate conditions for the storage of reagents and specimens for accurate and reliable test system operations and test result reporting. THE FINDINGS INCLUDE: 1. A review of the Temperature Records for July 2023 revealed that Freezer#2, with an expected temperature range of -15C - -18C, was outside of the acceptable temperature ranges 4 out of 31 days with no documented corrective actions. 2. A review of the December 2023 Temperature Records revealed that Freezer #1, with an established range of -20C, had 4 out of 31 failed temperatures with no documented corrective action. 3. A review of the December 2024 Temperature Records revealed Freezer #3, with an established range of -20C , had 1 out of 31 failed temperature. Also noted was Freezer#4, with a set range of -15C - -25 C , had 2 of 31 failed temperatures with no documented corrective actions. 4. A review of the February 2025 Temperature Records for Freezer#1, with a set range of -15C - -18C, revealed there was 1 out of 28 failed temperature and Freezer#2, with a set range of -15C - -18C, had 4 out of 28 failed temperatures with no documented corrective actions. 5. A review of the May 2025 Temperature Record revealed Freezer#1, with a set range of -20C, had 25 out of 31 temperature outside of temperature range. Also noted was Freezer#2, with a set range of -15C - -18C, had 4 out of 31 failed temperatures with no documented corrective actions. 6. A tour of the laboratory revealed that the Beckman Coulter Controls and Reagents have a storage requirement of -20C - -70C and were stored in Freezer#2, with a set temperature range of -15C - -18C. The documented temperatures reviewed for Freezer#3, with a set range of -20C, revealed in July 2023, December 2023, April 2024, December 2024, February 2025 and May 2025 temperatures were >-20C 161 times out of 182 days. 7. An exit interview, conducted with the Lab Team, on June 12, 2025, at 4:30pm confirmed that the laboratory failed to assure that conditions, essential for proper storage of reagents, were optimal for patient testing and reporting.
D5559	IMMUNOHEMATOLOGY CFR(s): 493.1271(e)(f) (e) Investigation of transfusion reactions. (e)(1) According to its established procedures, the laboratory that performs compatibility testing, or issues blood or blood products, must promptly investigate all transfusion reactions occurring in facilities for which it has investigational responsibility and make recommendations to the medical staff regarding improvements in transfusion procedures. (e)(2) The laboratory must document, as applicable, that all necessary remedial actions are taken to prevent recurrences of transfusion reactions and that all policies and procedures are reviewed to assure they are adequate to ensure the safety of individuals being transfused. (f) Documentation. The laboratory must document all control procedures

	performed, as specified in this section. This STANDARD is not met as evidenced by: A review of 2023 - 2025 Blood Bank Transfusion Records (BTR) confirmed that potential transfusion reactions were not identified, investigated, or reported as required. THE FINDINGS INCLUDE: 1. A review of The Transfusion Reaction Report (TRR), in use by the facility, lists the indicators of potential transfusion reactions. One listed indicator is a change in the systolic blood pressure by 20 - 30 mm /Hg. 2. A review of the Blood Bank Transfusion Reactions Procedure found that the procedure did not contain the established transfusion reaction indicators found on the TTR. 3. The review of the 2023 - 2025 BTR revealed thirteen (13) of thirteen (13) transfusion records had a change in blood pressure of 20 - 30+mm/Hg of their systolic pressure during the receipt of blood products. These patients included: a. MR#: 2175097 (DONOR UNIT#s RECEIVED: W0385 23 100779; W0385 23 100778; W0385 23 340865) b. MR#: 2179370 (DONOR UNIT# RECEIVED: W0385 23 700712) c. MR#: 2048366 (DONOR UNIT# RECEIVED: W0385 23 320551) d. MR#: 2001250 (DONOR UNIT# RECEIVED: W0385 24 701412) e. MR#: 2011061 (DONOR UNIT#s RECEIVED: W0385 24 352400; W0385 24 402400) f. MR#: 2189739 (DONOR UNIT# RECEIVED: W0385 25 802296) g. MR#: 2044943 (DONOR UNIT#s RECEIVED: W0385 25 330408; W0385 25 100428) h. MR#: 2121991 (DONOR UNIT# RECEIVED: W0385 25 800640) i. MR#: 2060956 (DONOR UNIT# RECEIVED: W0385 25 100296) 4. An interview with the General Supervisor confirmed that the Laboratory Director (LD)reviewed transfusion records monthly however there was no written documentation of review or investigation of the tranfusion reactions. 5. A review of the 13 transfusion records revealed that there was a failure in the identification or investigation of the potential reactions during the time of the transfusion. 6. A review of 13 of 13 completed TTRs forms revealed "No Reaction" was documented on all forms although the patients met at least one of transfusion reaction criteria for investigation. 7. An exit interview, with the Lab Team, on June 12, 2025, at 4:30pm confirmed that potential transfusion reactions were not identified, investigated, and reported as required.
D5793	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(b)(c) (b) The analytic 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 analytic systems quality assessment reviews with appropriate staff. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: A review of the Laboratory Blood Bank Procedure Title: Transfusion Reaction (TRP) and Blood Bank Transfusion Reaction Report (TRR), confirmed that the TRP failed to include the established indicators for a potential transfusion reaction. THE FINDINGS INCLUDE: 1. A review of the The Transfusion Reaction Protocol (page 3) revelaed "The transfusionist must be aware of the signs and symptoms of a transfusion reaction" jowever the procedure failed to specify the signs and symptoms of a transfusion reaction. 2. A review of the TRR revealed eleven (11) established indicators documented on the worksheet but were not documented in the TRP. 3. An exit interview, conducted with the Lab Team, on June 12, 2025, at 4:30pm confirmed

	that the TRP failed to include the established indicators of a potential transfusion reaction.
D6030	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(12) (e)(12) Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills; This STANDARD is not met as evidenced by: A review of 2023 - 2025 Personnel Records confirmed that the Laboratory Director (LD), failed to document training and competency assessments for personnel who conduct preanalytical, analytical, and postanalytical phases of testing. THE FINDINGS INCLUDE: 1. A review of the 2023 - 2024 Personnel Records revealed there were no available diplomas, degrees, and/ or transcripts for TC1, TP7, TP8, TP9, TP10, TP11, TP12, TP13, and TP14 (see CMS-Form 209 personnel form) to verify the qualifications of laboratory personnel. 2. A review of the 2023 - 2024 Personnel Records confirmed that 2023 and 2024 competencies were not available for riew for the main laboratory Testing Personnel (TP) which includes, TP1, TP2, TP3, TP4, TP5 and TP6, as identified on CMS-Form 209 Form. 3. A review of Personnel Records confirmed that competencies were not performed by qualified personnel on the Blood Gas Laboratory Testing Personnel, which includes TC1, TP7, TP8, TP9, TP10, TP11, TP12, TP13, and TP14, as identified on CMS-Form 209. 4. A review of the 2023 - 2024 Personnel Records revealed there were no competencies for years 2023, 2024, and 2025 for TC1, TP12, and TP14; 2023 competency for TP7; and 2024 competency for TP10. 5. An exit interview , with the Lab Team, on June 12, 2025, at 4:30pm confirmed that the LD failed to document training and competency assessments for personnel who conduct preanalytical, analytical, and postanalytical phases of testing.
D6076	LABORATORY DIRECTOR CFR(s): 493.1441 The laboratory must have a director who meets the qualification requirements of 493. 1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart. This CONDITION is not met as evidenced by: A review of 2023 - 2025 Personnel Records confirmed that Laboratory Director (LD) on Form 116 application dated June 10, 2025 failed to meet the LD qualifications as referenced in CLIA Regulation 493.1443. THE FINDINGS INCLUDE: 1. A review of the 2023 - 2025 Personnel Records revealed that the acting LD did not meet the required two (2) years of laboratory experience. 2. An exit interview conducted, with the Lab Team, on June 12, 2025, at 4:30pm confirmed that the LD, listed on the survey form 116, and CMS Personnel form 209, dated June 10, 2025, failed to meet the Laboratory Director qualifications.

D6079	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(a)(b) 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, record and report test results promptly, accurately and proficiently, and for assuring compliance with the applicable regulations. (a) The laboratory director, if qualified, may perform the duties of the technical supervisor, clinical consultant, general supervisor, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications under 493.1447, 493.1453, 493.1459, and 493.1487 respectively. (b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed. This STANDARD is not met as evidenced by: A review of 2023 - 2025 Quality Control Records, 2023 - 2025 Blood Bank Records, 2023 - 2025 Personnel Records, 2023 - 2025 API Proficiency Testing Records, 2023 - 2025 Maintenance Records, 2023 - 2025 Temperature Humidity Records and current Laboratory Procedure Manual confirmed that Laboratory Director (LD) failed to implement and perform effective oversight of the Preanalytical, Analytical and Postanalytical Systems of the laboratory. Refer to D2016, D2028, D2160, D5400, D5403, D5413, D5559, D5793, and D6030.