Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	11D0021371	04/09/2019
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 April 9, 2019. 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:
D3009	FACILITIES CFR(s): 493.1101(c) The laboratory must be in compliance with applicable Federal, State, and local laboratory requirements. This STANDARD is not met as evidenced by: Based on review of the laboratory director's credentials, education and experience as well as interview with the laboratory supervisor and hospital administrator, the laboratory director (LD) failed to meet the qualifications required by the state of Georgia to direct the laboratory. Findings include: 1. Review of the laboratory director's state license revealed it is a restricted license and was granted only to director the hospital laboratory in a nearby county. 2. Review of the the laboratory director's credentials revealed no documentation or evidence of certification by one of the credentialing boards required by the State of Georgia for laboratory directors. 3. Interview with the laboratory supervisor and hospital administrator on April 9, 2019 at approximately 11 am in the conference room confirmed the laboratory director is not certified by one agencies accepted by the State of Georgia, the LD has a restricted license and, therefore, is not qualified to direct this hospital laboratory.
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: Based on review of the laboratory's 2017, 2018 and 2019 quality control (QC) records for testing performed on the Beckman Coulter DXC600 chemistry & toxicology analyzers (DXC) , Beckman Coulter Access 2 Immunoassay analyzer (Access 2), and ACL coagulation analyzer (ACL) and review of the laboratory's 2017, 2018 & 2019 calibration verification documentation for testing performed on the DXC analyzers, the laboratory failed to monitor and evaluate the overall quality of the analytic systems and correct identified problem. Findings include: Refer to: D 5439 & D 5469
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 the initial opening comments and staff interview, it was stated that the laboratory had received a loaner analyzer for the Opti CCA TS Arterial Blood Gas (ABG) analyzer and also received a new ABG analyzer. There were no documents to show that the laboratory performed Accuracy, Precision, Reportable Range determination, and verification if the manufacturer's reference intervals were appropriate for the laboratory's patient population. Findings: 1. During the initial opening comments, it was stated that the laboratory had received a loaner ABG analyzer, and a replacement analyzer, when their analyzer was not working. I ask if they had the implementation documents and it was stated that they did not have any implementation documents. The only documents they could produce were two Quality Certificates, one for the loaner, and one for the new analyzer provided by the manufacturer. The blood gas supervisor was asked if they had any documents where they had verified the accuracy, precision, report range, and reference intervals, it was stated that they did not perform any verification on the analyzers. 2. Interview with the Blood Gas supervisor, on April 9, 2019 at approximately 12:15pm in the chapel, confirmed that the above aforementioned statement was correct.
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 laboratory's 2017, 2018 & 2019 calibration verification records, lack of documents and records to review and staff interview, the laboratory failed to document calibration verification of testing performed on the DXC 600 chemistry and toxicology analyzers. Findings include: 1. Review of calibration verification records revealed the only documentation available is a spread sheet showing the date of completion, name of the analyte, analytical range, and a low, mid-range and high value. No graphs, charts, instrument printouts or other documentation showing the actual values obtained during testing is available. 2. Review of calibration verification spread sheets revealed the analytical range recorded on the spread sheet does not correspond with the low and high values listed on the charts for some analytes. 3. Interview with the general supervisor on April 9, 2019 at approximately 4 pm in the conference room revealed the laboratory uses a combination of proficiency testing samples, calibrators and patient samples to perform calibration verification. No documentation or records showing the identity of the samples used, how values for the calibration verification material were established, or the acceptable limits for the difference between the measured value obtained, versus the actual concentration of the materials. 4. Review of the laboratory's procedure manuals revealed no procedure or instructions are available for performing calibration verification. 5. Interview with the general supervisor on April 9, 2019 at approximately 4:30 pm in the conference room confirmed the laboratory does not have documentation to support the values recorded on spreadsheets labeled DXC 600 Calibration Verification and does not have a procedure for performing calibration verification.
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(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--(d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed.

	This STANDARD is not met as evidenced by: Based on review of the Quality Control logs for the OPTI CCA TS blood gas (ABG) analyzer, the ABG Quality Control (QC) procedure and staff interview, the laboratory failed to document for the month of January 2018 and February 2018, that liquid controls were performed as stated in their ABG QC procedure as recommended by the manufacturer. Findings: 1. Review of the QC logs for the ABG analyzer showed that for the month of January and February in 2018, the laboratory did not document that liquid controls were performed in either month. 2. Interview with the Blood Gas supervisor on April 9, 2019 at approximately 3pm, in the chapel, confirmed that there was no documentation that the liquid ABG controls were performed in January and February of 2018.
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) procedure and QC documents for the Opti CCA TS analyzer used for testing Arterial Blood Gases (ABG's) , and staff interview , the laboratory failed to perform two levels of controls with different concentrations at least once each day patient specimens were assayed. Findings: 1. Review of the QC procedure and QC documents for the Opti CCA TS ABG analyzer revealed the laboratory only performed external liquid control monthly or when a new lot number was placed into use and did not perform two external controls of different concentrations each day of patient testing. 2. Interview with the laboratory general supervisor and respiratory therapy supervisor on April 9, 2019 at 12:15 pm in the Chapel confirmed the laboratory was not performing two levels of different concentrations of external controls at least once each day patient specimens were assayed. They also confirmed an Individualized Quality Control Plan (IQCP) had not been performed. 34123 Based on review of QC records for D-dimer testing performed using the Alere Triage Meter and staff interview , the laboratory failed to perform two levels of controls with different concentrations at least once each day patient specimens were assayed. Findings: 1. Review of QC records for D-dimer testing performed on the Alere Triage meter revealed QC was only performed monthly and when a new kit or lot number was placed into use. 4. Interview with the laboratory general supervisor (see CMS 209) on April 9, 2019 at 6 pm in the conference room confirmed the laboratory was not performing two levels of different concentrations of controls at least once each day patient specimens were assayed and also confirmed an Individualized Quality Control Plan (IQCP) had not been performed.
D5469	CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(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-- Establish or verify the criteria for acceptability of all control materials. (i) When

	control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of the laboratory's 2017, 2018 and 2019 quality control (QC) records for testing performed on the Beckman Coulter DXC600 chemistry & toxicology analyzers (DXC) , Beckman Coulter Access 2 Immunoassay analyzer (Access 2), and ACL coagulation analyzer (ACL), review of the package inserts for controls, review of the manufacturer's instructions for use of controls and staff interview, the laboratory failed to establish criteria for acceptability of controls. Findings include: 1. Review of 20017, 2018 & 2019 Levey Jennings charts for testing performed on the DXC chemistry analyzer, DXC toxicology analyzer, Access 2 immunoassay analyzer and ACL coagulation analyzer, review of BioRad control assay sheets including Liquid Assayed Multiqual control, Immunoassay Plus control , and Liquicheck Diabetes control , Liquicheck Cardiac Markers Plus control, Liquicheck Ethanol /Ammonia control, Liquicheck Urine Chemistry control, and review of Hemosil coagulation control assay sheets, revealed the laboratory uses the standard deviation (SD) and ranges given by the manufacturer on the assay sheet to determine the acceptable range of control values and has not adjusted their QC ranges to reflect the standard deviation obtained by their laboratory. 2. Review of control values obtained by the laboratory also revealed the standard deviations calculated on testing performed in their laboratory is much lower than the values used to determine acceptability of patient results. 3. Review of on-line instructions for Biorad controls listed above and obtained from BioRad at www.myeinserts.com and review of manufacturer's instructions for use of Hemosil coagulation controls revealed each laboratory should establish their own acceptable ranges and use the assayed ranges as a guide. 4. Interview with the general supervisor (see CMS 209) on April 9, 2019 at 12 pm in the conference room confirmed the laboratory uses the mean and SD ranges from the assay sheets supplied by the manufacturer and those ranges are not indicative of ranges obtained by their laboratory.
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: Based on review of laboratory records, lack of records to review and staff interview, the laboratory director failed to provide overall management and direction of the laboratory. Findings include: Refer to D 6093 & D 6106
D6093	LABORATORY DIRECTOR RESPONSIBILITIES

	CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality control 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: Based on review of the laboratory's 2017, 2018 and 2019 quality control (QC) records for testing performed on the Beckman Coulter DXC600 chemistry & toxicology analyzers (DXC) , Beckman Coulter Access 2 Immunoassay analyzer (Access 2), and ACL coagulation analyzer (ACL), review of the package inserts for controls, review of the manufacturer's instructions for use of controls and staff interview, the laboratory director failed to ensure the laboratory established criteria for acceptability of controls. Also, based on review of QC records for D-dimer testing performed using the Alere Triage Meter and staff interview , the laboratory director failed to ensure the laboratory performed two levels of controls with different concentrations at least once each day patient specimens were assayed. Refer to D 5469 & D 5447
D6106	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(14) The laboratory director must ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process. This STANDARD is not met as evidenced by: Based on review of the laboratory's policy and procedure manuals and staff interview, the laboratory director failed to ensure a procedure was available for performing calibration verification for testing performed on the DXC 600 chemistry and toxicology analyzers. Findings include: 1. Review of the laboratory's procedure manuals revealed no procedure or instructions available for performing calibration verification for testing performed on the DXC 600 chemistry and toxicology analyzers. 2. . Interview with the general supervisor on April 9, 2019 at approximately 4:30 pm in the conference room confirmed the laboratory does not have a procedure for performing calibration verification on the DXC analyzers. Also refer to: D 5439