

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  11D0021371	<b>(X3) Date Survey Completed</b>  05/11/2023
<b>Name of Provider or Supplier</b>  Screven County Hospital, Llc	<b>Street Address, City, State</b>  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.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D0000</b>	A Clinical Laboratory Improvement Amendments (CLIA) recertification survey was completed on May 11, 2023. 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:
<b>D5209</b>	<p><b>PERSONNEL COMPETENCY ASSESSMENT POLICIES</b> CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p> <p>This STANDARD is not met as evidenced by: Based on competency document review and staff interview, the Laboratory Director failed to ensure competency was reviewed and signed for 2021. Findings include: 1. Competency document review revealed the Laboratory Director did not review or sign the competency documents for Testing Personnel #5 (CMS-209) in 2021. 2. During an interview with the General Supervisor (CMS-209) on May 11, 2023 at 2:30 PM, in the GS office, confirmed the lack of the Laboratory Director's review and signature of the competency document for 2021.</p>
<b>D5293</b>	<p><b>GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT</b> CFR(s): 493.1239(b)(c)</p> <p>(b) The general laboratory 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 general laboratory systems quality assessment reviews with appropriate staff. (c) The laboratory must document all general laboratory systems quality assessment activities.</p>

This STANDARD is not met as evidenced by:  
Based on quality assessment (QA) document review and staff interview, the laboratory failed to document quality assessment activities as required. The Findings include: 1. Laboratory QA document review revealed the lack of a QA checklist for 2021 (January 2021- December 2021) and 2022 (January 2022-December 2022), and thus far 2023 (January-May 2023). 2. During an interview, on May 11, 2023, with the General Supervisor (CSM-209) at 2:00 PM, in the breakroom, confirmed the lack of a QA checklist for 2021, 2022, and thus far 2023.

**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:  
Based on temperature record review and staff interview, the laboratory failed to ensure freezer #1, freezer #2, and freezer #3 were within in normal range. The Findings include: 1. Temperature records revealed freezer #1 was out range for 29 out of 31 days. The freezer range is less than -20 degrees Celsius. 2. Temperature records revealed freezer #2 was out of range for 9 out of 31 days. The freezer range is (-15-(-18))degrees Celsius. 3. Temperature records revealed freezer #3 was out of range for 6 out of 31 days. The freezer range is less than -20 degrees Celsius. 4. During an interview with General Supervisor (CMS-209) on May 11, 2023 at approximately 2:15 PM, confirmed the freezer ranges were out of range for freezer #1, freezer #2, and freezer #3 without corrective action.

**D5791**

**ANALYTIC SYSTEMS QUALITY ASSESSMENT**  
CFR(s): 493.1289(a)(c)

(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 analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities.

This STANDARD is not met as evidenced by:  
Based on Quality Assessment (QA) document review and staff interview, the laboratory failed to document quality assessment activities, on a monthly basis, as stated in their QA policy manual from January to December 2021, January to December 2022, and January - May 2023. Findings: 1. A review of the laboratory QA documents revealed the technical supervisor (TS) did not review and sign monthly quality activity checklists for 2021, 2022, and 2023. 2. There were no monthly review logs signed for Room Temperature, Humidity, Eye Wash or Refrigerator during the day of survey, May 11, 2023. 3. During an interview with the General Supervisor (CMS 209), on May 11, 2023, at approximately 1:40 PM, in the the General

Manager's office, confirmed the laboratory director/technical consultant did not review and sign monthly quality activity checklists for temperature, freezer, refrigerator, or water system checks.

**D6103**

**LABORATORY DIRECTOR RESPONSIBILITIES**

CFR(s): 493.1445(e)(13)

The laboratory director must 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:

Based on competency document review and staff interview, the Laboratory Director failed to ensure competency records was reviewed and signed. The Findings include:  
1. Competency document review revealed the Laboratory Director (LD) failed to ensure the competency records were reviewed and signed for Testing Personnel #5 in 2021. 2. During an interview with General Supervisor (CMS-209) on May 11, 2023, at 2:00 PM, in the GS office, confirmed the Laboratory Director (LD) did not review or sign the competency record for Testing Personnel #5 in 2021.