

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 11D0022344	(X3) Date Survey Completed 01/25/2024
Name of Provider or Supplier Lifebrite Community Hospital Of Early	Street Address, City, State 11740 Columbia Street, Blakely, 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	<p>A recertification survey was performed on January 25, 2024. The facility was found to be NOT in compliance with the CLIA conditions and standards for specialties /subspecialties for 42 CFR. Condition: 493.1255b -Calibration and Calibration Verification NOTE: The CMS-2567 (Statement of Deficiencies) is an official , legal document,. All information must remain unchanged except for entering the Plan Of Correction (POC), correction dates, and the signature space. Any discrepancy n the original deficiency citation(s) will be reported the the Georgia Regional Office (RO) for referral the Office of the Inspector General (OIG) for possible fraud if the information is inadvertently changed by the provide/supplier, the State Survey Agency (SA) should be notified immediately.</p>
D2009	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods.</p> <p>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 provide signed copies of the required Attestation Statements for 2022 - 2023 for Chemistry, Hematology/Coag, Microbiology, Immunology, and Chemistry Miscellaneous PT testing, Findings: 1. Review of the 2022 PT documents revealed that the Attestation statements for 2022, were not signed for the following events, and Specialty: 2022 for Chemistry - Events 1 and 2 were not signed by the Laboratory Director (LD) 2022 for Hematology /Coagulation - Event 1, was not signed by the LD or Testing Personnel (TP) Event 2 and 3 were signed by the TP, but not the LD 2022 for Microbiology - Events 1 and 2, did not have signed attestation statements 2022 Immunohematology - Event 2, did not have a signed attestation statement by the LD 2. Review of the 2023 PT documents</p>

showed that the Attestation statements for 2023, were not signed for the following events, and Specialty: 2023 for Chemistry - Event 1, did not have an attestation statement Events 2 and 3, did not have an attestation signed by the LD. 2023 for Hematology - Events 1 and 3 did not have an attestation statement signed by the LD 2023 for Microbiology - Events 1 and 3 did not have an attestation statement signed by the LD 2023 Immunohematology - Events 1 and 2 did not have an attestation statement signed by the LD 2023 Chemistry Miscellaneous - Event 1 did not have an attestation statement signed by the LD. 3. Interview with the Laboratory Supervisor, at approximately 1pm, on 01/26/2024, in the Medical Records Department, confirmed the above aforementioned statements.

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 Calibration and Linearity documents for Chemistry, the laboratory failed to monitor and evaluate the overall quality of the analytic systems for each specialty and subspecialty of testing performed. Condition Level Deficiency 493.1255 b Calibration and Calibration Verification REFERENCE: D-5439

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 Chemistry Calibration Verification / Linearity Documents and staff interview the laboratory failed to provide documentation for the every 6 months linearity performance for each analyte that does not have at least three levels of calibrator samples, that cover the low, mid, and high range of the analyte performance. Findings: 3. Review of the Chemistry Linearity Documentation, the Laboratory performed Calibration Verification and Linearity studies in Chemistry every 6 months in 2022, but there was no documentation for 2023. 2. Interview with the Laboratory Supervisor, on 01/26/2024, at approximately 1:30 pm, in the Medical Record Department, confirmed the above aforementioned statement.

D6007

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(1)

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)(1) Ensure that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the preanalytic, analytic, and postanalytic phases of testing;

This STANDARD is not met as evidenced by:

Based on review of the American Proficiency Institute (API) Proficiency Testing (PT) documents for 2022, and 2023, Calibration Verification/ Linearity documentation for the Specialty of Chemistry, and staff interview, the PREVIOUS Laboratory Director (LD) failed to ensure that testing systems used for the specialty of Chemistry, for each analyte performed in the laboratory provided quality laboratory services. Findings: 1. Review of the 2022 PT documents showed that the Attestation statements for 2022, were not signed for the following events, and Specialty: 2022 for Chemistry - Events 1 and 2 were not signed by the Laboratory Director (LD) 2022 for Hematology /Coagulation - Event 1, was not signed by the LD or Testing Personnel (TP) Event 2 and 3 were signed by the TP, but not the LD 2022 for Microbiology - Events 1 and 2, did not have signed attestation statements 2022 Immunohematology - Event 2, did not have a signed attestation statement by the LD 2. Review of the 2023 PT documents showed that the Attestation statements for 2023, were not signed for the following events, and Specialty: 2023 for Chemistry - Event 1, did not have an attestation statement Events 2 and 3, did not have an attestation signed by the LD. 2023 for Hematology - Events 1 and 3 did not have an attestation statement signed by the LD 2023 for Microbiology - Events 1 and 3 did not have an attestation statement signed by the LD 2023 Immunohematology - Events 1 and 2 did not have an attestation statement signed by the LD 2023 Chemistry Miscellaneous - Event 1 did not have an attestation statement signed by the LD. 3. Review of the Chemistry Linearity Documentation, the Laboratory performed Calibration Verification and Linearity studies in Chemistry every 6 months in 2022, but there was no documentation for 2023. 4. Interview with the Laboratory Manager, on January 26, 2024 at approximately 1:45 pm in the Medical Records area, confirmed the aforementioned statements. The current LD was recently employed on 01/01/2024.