Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 11D0022344	**(X3) Date Survey Completed** 10/08/2019
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	A Clinical Laboratory Improvement Amendments (CLIA) Recertification survey was completed on October 8-9, 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:
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on review of the laboratory policy and procedure manual (SOP) the laboratory failed to include all required procedures for laboratory testing. Findings include: 1. SOP review reveals the laboratory failed to specify in writing the corrective action of

	an inoperable test system or a retention policy. 2. An interview with the general supervisor (CMS 209) in the medical records room on 10/8/19 at approximately 5:20 p.m. confirmed the SOP did not contain the aforementioned procedures.
D5431	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(2) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document function checks as defined by the manufacturer and with at least the frequency specified by the manufacturer. Function checks must be within the manufacturer's established limits before patient testing is conducted. This STANDARD is not met as evidenced by: Based on review of the maintenance logs for the DxH600 Hematology analyzer (DxH600), and staff interview, the laboratory failed to document monthly maintenance for January, February, March, April, May, July, and August 2019. Findings: 1. Review of the maintenance logs for the DxH600, revelead that there was no documented monthly maintenance performed in 2019 for January, February, March, April, May, July, or August. 2. Interview with the general supervisor (CMS209) and hospital administrator, on 10/08/2019, at approximately 5:00 pm, in the medical records department, confirmed that there was no documentation of monthly maintenance performed on the DxH600, for the months stated above.
D5555	IMMUNOHEMATOLOGY CFR(s): 493.1271(c)(f) (c) Blood and blood products storage. Blood and Blood products must be stored under appropriate conditions that include an adequate temperature alarm system that is regularly inspected. (c)(1) An audible alarm system must monitor proper blood and blood product storage temperature over a 24-hour period. (c)(2) Inspections of the alarm system must be documented. (f) Documentation. The laboratory must document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: Based on review of the Procedure #LAB-P8058 "Quality Control: Blood Bank Refrigerator and Freezer", review of the Blood Bank (BB) alarm checks, review of the Policy and Procedure #LAB-P8062 "Storage of Blood Components in the event of the loss of monitored refrigeration", and staff interviews, the laboratory was not following procedures for documenting the alarm checks, or documenting manual temperatures for the alternate refrigerator used when the monitored refrigerator was not working. Findings: 1. Review of the BB procedure #LAB-P8058, indicates that the high temperature for the alarm activation must be checked and documented using the procedure #LAB-P8058. There was no documentation of the actual temperature in which the alarm sounded for the high temp activation or low temp activation. The alarm check consisted of a date, time, tech, person responding, and review. 2. Review of Procedure #LAB-P8062, indicates "record the temperature, time, and initial the temperature log every hour". Review of the Blood Bank Refrigerator Event, January 4, 2018 log indicated the blood and reagents were moved to the toxicology refrigerator. The date and time the temperature was checked was documented every four (4) hours rather than every hour as stated in the Procedure #LAB-P8062 3. Interview with the general supervisor (CMS209) and the hospital administrator, on 10

	/08/2019, at approximately 4:55 pm, in the medical records department, confirmed the aforementioned documentation.
D5783	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(2) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results. This STANDARD is not met as evidenced by: Based on Quality Control (QC) document review and staff interview, the laboratory failed to document corrective actions when QC was out of limits. Findings include: 1. Review of QC documents in hematology reveals QC was out of range without corrective actions documented on 7/04/18, 7/22/18, 7/27/18, 12/23/18, 3/22/19, 5/9/19, or 5/21/19. 2. An interview with the general supervisor (CMS 209) in the medical records room on 10/8/19 at approximately 5:20 p.m. confirmed the aforementioned corrective actions were not documented.
D6082	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(1) The laboratory director must 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 Installation/Implementation manuals for the two AU6400's, Toxicology analyzers, the DxH600, and staff interview, the Laboratory Director (LD) failed to document the acceptance of the verification performance for all new test systems. Findings 1. Review of the installation/implementation manuals for the two AU6400's, toxicology analyzers, and the DxH600 hematology analyzer, revealed that the LD did not approve the implementation of the AU6400, toxicology analyzers, or the DxH600 analyzer. AU6400, serial number 3072310, was signed by the Toxicology Supervisor at the time of installation. 2. Interview with the general supervisor (CMS209), and the hospital administrator, on 10/8/2019, at approximately 5:05 pm in the medical records department, confirmed that the implementation documents for the two AU6400's, and the DxH600 was not signed by the LD.
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 policy and procedure manuals (SOPs) and staff interview, the laboratory director (LD) failed to sign and approve procedures. Findgs include: 1. SOP reviews revealed the LD failed to ensure that signed and approved procedure manuals are available to all testing personnel 2. An interview with the general supervisor (CMS 209) in the medical records room on 10/8/19 at approximately 5:20 p.m. confirmed the SOP was not signed or approved by the lab director. Based on review of the Blood Bank(BB) Procedure, #LAB-P8064 "Daily Blood Bank Reagent quality control", and staff interview, the Laboratory Director (LD) failed to sign a revision in the procedure. Findings: 1. Review of the policy and procedure #LAB-P8064, showed that the frequency of BB Quality Control was revised from DAILY to "as needed". The LD had not signed the revision as being approved. 2. An interview with the general supervisor (CMS209) and the hospital administrator, on 10/08/2019, at approximately 5:10 pm, confirmed that the LD had not signed the revision in #LAB-P8064 procedure
D6107	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(15) The laboratory director must specify, in writing, the responsibilities and duties of each consultant and each supervisor, as well as each person engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or result reporting and whether supervisory or director review is required prior to reporting patient test results. This STANDARD is not met as evidenced by: Based on review of the laboratory policy and procedure manual (SOP) and staff interview, the laboratory director (LD) failed to specify, in writing the duties and responsibilities of each person engaged in the performance of the preanalytic, analytic, and postanalytic phases of laboratory testing. Findings include: 1. SOP review revealed the LD failed to specify in writing the duties and responsibilities of each person engaged in the performance of all phases of laboratory testing. 2. An interview with the general supervisor (CMS 209) in the medical records room on 10/8/19 at approximately 5:20 p.m. confirmed the SOP did not contain a duties and responsibilities policy and procedure.
D6127	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(9) The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: Based on review of testing personnel documents and an interview with the general supervisor, the technical supervisor (TS) failed to perform semi-annual competency on all testing personnel. Findings include: 1. Review of testing personnel documents reveals the TS did not perform a 6 month competency evaluation on staff #3 and Staff #6 (CMS 209 form) during 2018. 2. An interview with the general supervisor (CMS

	209) in the medical records room on 10/8/19 at approximately 12:30 p.m. confirmed the the aforementioned missing competency evaluations.
D6175	TESTING PERSONNEL RESPONSIBILITIES CFR(s): 493.1495(b)(1) Each individual performing high complexity testing must follow the laboratory's procedures for specimen handling and processing, test analyses, reporting and maintaining records of patient test results. This STANDARD is not met as evidenced by: Based on review of the Blood Bank (BB) log book, and staff interview, the testing personnel did not initial when performing the ordered test. Findings: 1. Review of the BB log book, on October 2, 2018, revealed that on the 4th line from the top, the patient had an ABO, rH, and an antibody screen performed. There are no initials confirming the testing personnel. 6th line from the top, the patient had an ABO, rH testing performed with no initials confirming the testing personnel. 12 line from the top, the patient had an ABO, rH, antibody screen with no initials confirming the testing personnel. 2. Interview with the general supervisor (CMS209), and the hospital administrator, on 10/08/2019, at approximately 5:10 pm, in the medical records department, confirmed that there were no initials by testing personnel for the above mentioned patients.