Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	11D0022344	04/05/2022
Name of Provider or Supplier	**Street Address, City, State**	
Lifebrite Community Hospital Of Early	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 March 4, 2022. 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: Based on review of the American Proficiency Institute (API) Proficiency Testing (PT) documents for 2021, second event for the Speciality Immunohematology, sub-specialty Compatibility Testing, the laboratory obtained a score less than 100% which is an unsatisfactory performance. Reference: D2173

D2173	COMPATIBILITY TESTING CFR(s): 493.863(a) Failure to attain an overall testing event score of at least 100 percent is unsatisfactory performance. This STANDARD is not met as evidenced by: Based on review of the American Proficiency Institute (API) Proficiency Testing (PT) documents for 2021, second event for the Speciality Immunohematology, sub-specialty Compatibility Testing, the laboratory obtained a score less than 100% which is an unsatisfactory performance. Findings: 1. Review of the APT PT documents for the year 2021 second event, the laboratory received a score of 80% for the sub-specialty of Compatibility Testing. 2. Interview with the laboratory Manager, on April 5, 2022, at approximately 2pm in the laboratory confirmed the aformentioned statement.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on review of the Blood Bank (BB) Quality Control (QC), for the year 2020, the laboratory performed the QC with expired reagents and performed BB testing with the same expired reagents. Findings: 1. Review of the BB QC log for the year 2020, the laboratory performed QC using expired Anti-A reagent on April 27, 2020. The reagent expired on April 21, 2020. Compatibility Testing for two units of blood, was performed, using the expired reagent, and the two units were transfused, on April 27, 2020. 2. Interview with the Laboratory Manager on April 5, 2022, at approximately 2 pm in the laboratory confirmed the aforementioned statement.
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 the American Proficiency Institute (API) Proficiency Testing (PT) documents for the year 2021, second event, for the sub-speciality Compatibility Testing, and the Blood Bank (BB) Quality Control (QC) log sheet for April 27, 2020. The Laboratory Director (LD) failed to provide overall management and direction in the laboratory. Findings: 1. Review of the APT PT documents for the year 2021 second event, the laboratory received a score of 80% for the sub-specialty of Compatibility Testing. 2. Review of the BB QC log for the year 2020, the laboratory performed QC using expired Anti-A reagent on April 27, 2020. The reagent expired on April 21 2020. Compatibility Testing for two units of blood, was performed, using

	the expired reagent, and the two units was transfused, on April 27, 2020. 3. Interview with the Laboratory Manager, on April 5, 2022, at approximately 2:15 pm, in the Laboratory confirmed the aforementioned statements.