Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	11D0022344	03/03/2026
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 3, 2026. 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:
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) (b)(1) 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. This STANDARD is not met as evidenced by: A review of the 2024 - 2026 API Proficiency Testing Records confirmed that the laboratory failed to attest to the routine integration of the samples into the patient workload using the laboratory's routine methods. THE FINDINGS INCLUDE: 1. A review of the 2024 - 2026 API Proficiency Testing Records revealed seven (7) of eight (8) Proficiency Testing Attestation statements were unsigned by the Laboratory Director. 2. An exit interview, with Lab Staff, on March 3, 2026, at 3:00pm confirmed that the Laboratory Director failed to attest to the routine integration of the samples into the patient workload using the laboratory's routine methods.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) (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: (b)(1) Water quality. (b)(2) Temperature. (b)(3)

	Humidity. (b)(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: A tour of the laboratory confirmed that the laboratory failed to store reagents/ specimens as required by the manufacturer. THE FINDINGS INCLUDE: 1. A tour of the facility confirmed that in-use and/ or stored reagents and supplies, with temperature storage requirements, were in locations in which the temperature was not monitored. 2. The facility tour revealed the following agents in the Drawing Station : a. Becton Dickinson (BD) EDTA Vacutainer Tubes, BD EDTA Pediatric Vacutainer Vials, BD Sodium Citrate Vacutainer Tubes, BD Serum Separator Vacutainer Tubes, BD Lithium Heparin Vacutainer Tubes, BD SST Vacutainer Tubes, and BD Red Serum Vacutainer Tubes, with a storage temperature requirement of 4C - 25C 3. The facility tour revealed the following agents in the Reagent Storage Room : a. Becton Dickinson (BD) EDTA/ K2EDTA Vacutainer Tubes, BD EDTA Pediatric Vacutainer Vials, BD K2E 5.4mg vacutainer Tubes, BD Sodium Citrate Vacutainer Tubes, BD Serum Separator Vacutainer Tubes, BD Lithium Heparin Vacutainer Tubes, BD Red Serum Vacutainer Tubes, BD SST Vacutainer Tubes, Greiner Bio-One Sodium Fluoride/ Potassium Oxalate Vacutainer Tubes, Becton Dickinson (BD) EDTA/ K2EDTA Microtainer Tubes, BD Lithium Heparin Microtainer Tubes, BD SST Microtainer Tubes, with a storage temperature requirement of 4C - 25C. b. Accu-Chek Inform II Glucose Test Strips, with a storage temperature requirement of 4C - 30C. c. Para-Pak C&S Transport Vial, with a storage temperature requirement of 2C - 30C. d. Para-Pak 10% Buffered Formalin Ova & Parasite Stool Specimen Transport Vials with a storage temperature requirement of15C - 30C 4. An exit interview, with Lab Staff, on March 3, 2026, at 3:00pm confirmed that the laboratory failed to store reagents/ specimens/ etc. as mandated by the manufacturer.
D6020	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) (e)(5) Ensure that the quality control and quality assessment 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: A review of the API Proficiency Test Records, Maintenance Records, Quality Control Records, Quality Assurance, Personnel Records and Temperature Records for years 2024 - 2026 confirmed that the Laboratory Director failed to ensure that the quality control and quality assessment programs are established and maintained. THE FINDINGS INCLUDE: 1. A review of the aforementioned 2024 - 2026 laboratory records confirmed the lack of Laboratory Director's quality assurance review. 2. A review of the 2024 - 2026 laboratory records revealed that quality assurance review was performed by the General Supervisor without written delegation of such duties by the Laboratory Director. 3. An exit interview, with Lab Staff, on March 3, 2026, at 3: 00pm confirmed that the Laboratory Director failed to ensure that the quality control and quality assessment programs are established and maintained.
D6079	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(a)(b)

	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, record and report test results promptly, accurately and proficiently, and for assuring compliance with the applicable regulations. (a) The laboratory director, if qualified, may perform the duties of the technical supervisor, clinical consultant, general supervisor, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications under 493.1447, 493.1453, 493.1459, and 493.1487 respectively. (b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed. This STANDARD is not met as evidenced by: A review of the API Proficiency Test Records, Maintenance Records, Quality Control Records, Quality Assurance, Personnel Records and Temperature Records for the laboratory for the period of Year 2024 - Year 2026 review period confirmed that the Laboratory Director failed to conduct successful oversight of the overall operation and administration of the laboratory. Reference: D2009, D5413, D6020, and D6063 .