Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D2261995	01/18/2023
Name of Provider or Supplier	**Street Address, City, State**	
Er Care Cfl Llc	7780 Lake Underhill Rd Suite 111, Orlando, FL	

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	An initial certification survey was conducted on January 18, 2023. ER Care CFL LLC clinical laboratory was not in compliance with 42 CFR 493, requirements for clinical laboratories.
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 record review, and interview, the laboratory's procedure manual failed to include a list of the critical (alert) values from 08/24/2022 to 01/18/2023. Findings: Review of the laboratory's procedure manual showed the manual was signed and dated by the Laboratory Director on 08/01/2022. Review of the procedure titled,

	"Critical Values" showed the policy failed to list the critical values for tests performed in the laboratory. Review of the Critical Values policy noted, "This laboratory has determined that NO tests performed have potentially life-threatening results, require immediate medical attention, or change in treatment. Therefore, there are no critical values." The laboratory performed the following moderate complexity testing which had critical values: white blood cell count (WBC), hemoglobin, hematocrit, platelet count, sodium, potassium, chloride, ionized calcium, glucose, blood urea nitrogen (BUN), creatinine, total carbon dioxide (CO2) and troponin. On 01/18/2023 at 12:10 PM, Technical Consultant A acknowledged some of the tests they performed had critical values and did not have a list of critical values that was specific for their laboratory.
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 observation, record review, and interview, the laboratory failed to properly label quality control bottles currently in use in Hematology from 08/24/2022 to 01/18 /2023. Findings: A tour of the laboratory on 01/18/2023 at 9:35 AM, revealed the low, normal, and high Boule Con-Diff Tri-Level Controls (low control lot #22210-01, normal control lot #22210-02 & high control lot #22210-03) for the Medonic M Series Hematology analyzer did not have the open date or new expiration date on the opened vials. Review of the package insert for the Boule Con-Diff Tri-Level Controls noted, "Open vial stability 14 days after opening when returned to refrigerator after each use." According to the Clinical Laboratory Improvement Amendments (CLIA) Application for Certification, signed and dated by the Laboratory Director on 01/06 /2023, the laboratory had a total estimated annual test volume of 6,000 hematology tests per year. On 01/18/2023 at 9:40 AM, Technical Consultant A stated they did not record the opened date or the new opened expiration date on the controls.
D5781	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population.

This STANDARD is not met as evidenced by:
Based on record review, and interview, the laboratory failed to document corrective actions for freezer temperatures that were not within the acceptable temperature range from 08/24/2022 to 01/18/2023, for 164 of 167 days. Findings: During a tour of the laboratory on 01/18/2023 at 9:35 AM, the Triage Total 5 Control 1, Triage Total 5 Control 2, and Triage BNP Control 1 were observed being stored in the freezer. The boxes containing the controls indicated the stored temperature should be -20 degrees Celsius (C) or below. The laboratory used the Quidel Triage chemistry analyzer to test for Troponin and D-Dimer. Review of the "Temperature and General Maintenance" logs for the laboratory showed the temperature of the freezer was not cold enough or not recorded for the following dates. 08/01/2022 temperature -14 degrees C 08/02 /2022 temperature -14 degrees C 08/03/2022 temperature -17 degrees C 08/04/2022 temperature -12 degrees C 08/05/2022 temperature -16 degrees C 08/06/2022 temperature -16 degrees C 08/07/2022 temperature -16 degrees C 08/08/2022 temperature -16 degrees C 08/09/2022 temperature -13 degrees C 08/10/2022 temperature -18 degrees C 08/11/2022 temperature -18 degrees C 08/12/2022 temperature -14 degrees C 08/13/2022 temperature -14 degrees C 08/14/2022 temperature -13 degrees C 08/15/2022 temperature -13 degrees C 08/16/2022 temperature -13 degrees C 08/17/2022 temperature -13 degrees C 08/18/2022 temperature -16 degrees C 08/19/2022 temperature -12 degrees C 08/20/2022 temperature -16 degrees C 08/21/2022 no temperature was recorded 08/22/2022 temperature -11 degrees C 08/23/2022 temperature -13 degrees C 08/24/2022 temperature -13 degrees C 08/25/2022 temperature -16 degrees C 08/26/2022 no temperature was recorded 08/27/2022 temperature -18 degrees C 08/28/2022 temperature -17 degrees C 08/29/2022 temperature -17 degrees C 08/30/2022 temperature -17 degrees C 08/31/2022 temperature -16 degrees C 09/01/2022 temperature -16 degrees C 09/02/2022 temperature -16 degrees C 09/03/2022 temperature -18 degrees C 09/04/2022 temperature -15 degrees C 09/05/2022 temperature -15 degrees C 09/06/2022 temperature -15 degrees C 09/07/2022 temperature -15 degrees C 09/08/2022 temperature -15 degrees C 09/09/2022 temperature -18 degrees C 09/10/2022 temperature -14 degrees C 09/11/2022 temperature -14 degrees C 09/12/2022 temperature -11 degrees C 09/13/2022 temperature -16 degrees C 09/14/2022 temperature -17 degrees C 09/15/2022 temperature -13 degrees C 09/16/2022 temperature -13 degrees C 09/17/2022 temperature -13 degrees C 09/18/2022 temperature -17 degrees C 09/19/2022 temperature -11 degrees C 09/20/2022 temperature -11 degrees C 09/21/2022 temperature -12 degrees C 09/22/2022 temperature -12 degrees C 09/23/2022 temperature -15 degrees C 09/24/2022 temperature -15 degrees C 09/25/2022 temperature -15 degrees C 09/26/2022 temperature -17 degrees C 09/27/2022 temperature -15 degrees C 09/28/2022 temperature -15 degrees C 09/29/2022 temperature -14 degrees C 09/30/2022 temperature -18 degrees C 10/01/2022 temperature -14 degrees C 10/02/2022 temperature -14 degrees C 10/03/2022 temperature -14 degrees C 10/04/2022 temperature -18 degrees C 10/05/2022 temperature -15 degrees C 10/06/2022 temperature -18 degrees C 10/07/2022 temperature -18 degrees C 10/08/2022 temperature -18 degrees C 10/09/2022 temperature -12 degrees C 10/10/2022 temperature -13 degrees C 10/11/2022 temperature -16 degrees C 10/12/2022 temperature -16 degrees C 10/13/2022 temperature -16 degrees C 10/14/2022 temperature -16 degrees C 10/15/2022 temperature -14 degrees C 10/16/2022 temperature -11 degrees C 10/17/2022 temperature -18 degrees C 10/18/2022 temperature -10 degrees C 10/19/2022 temperature -14 degrees C 10/20/2022 temperature -18 degrees C 10/21/2022 temperature -18 degrees C 10/22/2022 temperature -18 degrees C 10/23/2022 temperature -10 degrees C 10/24/2022 temperature -14 degrees C 10/25/2022

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D5807	TEST REPORT CFR(s): 493.1291(d) Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results. This STANDARD is not met as evidenced by:

	Based on record review, and interview, the laboratory failed to list the normal values of the laboratory tests for three of three (#1, #2, #3) patients' laboratory test reports who had chemistry testing done. Findings: Review of three patients' laboratory test results showed the normal values for tests run using the Chem 8+ cartridge on the Abbott i-Stat were not listed on the test reports. The Chem 8+ cartridge test for sodium, potassium, chloride, ionized calcium, glucose, blood urea nitrogen (BUN), creatinine, and total carbon dioxide (CO2) On 01/18/2023 at 1:43, Technical Consultant A stated the normal values were not listed on the test reports given to patients.