

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  10D2261995	<b>(X3) Date Survey Completed</b>  12/09/2024
<b>Name of Provider or Supplier</b>  Er Care Cfl Llc	<b>Street Address, City, State</b>  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.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D0000</b>	A recertification survey was conducted on 11/20/2024 to 12/9/2024. ER Care of CFL LLC clinical laboratory was not in compliance with 42 CFR 493, requirements for clinical laboratories.
<b>D3037</b>	<p><b>RETENTION REQUIREMENTS</b> CFR(s): 493.1105(a)(4)</p> <p>Proficiency testing records. Retain all proficiency testing records for at least 2 years.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to maintain the American proficiency institute (API) testing records for the 2nd event of Chemistry in 2023 and 2nd event of Hematology in 2024. Findings Included: Review of API proficiency testing record revealed no documentation of a proficiency testing packet for the 2nd event of Chemistry in 2023 and 2nd event of Hematology in 2024. Review of Record Retention Policy stated, " Following is a listing of all records to be retained and the minimum period of time-proficiency testing - 2 years." On 11/20/2024 at 2:34 PM, the physician assistant confirmed proficiency testing was not maintained for the 2 years for the 2nd event of Chemistry in 2023 and 2nd event of Hematology in 2024.</p>
<b>D5429</b>	<p><b>MAINTENANCE AND FUNCTION CHECKS</b> CFR(s): 493.1254(a)(1)</p> <p>For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interviews, the laboratory failed to document the daily</p>

quality control maintenance, monthly maintenance, six month maintenance and calibration maintained to ensure it was completed for Mesonic M-series Hematology from October 2023 to November 2024. Findings Included: Review of Medonic M-Series Hematology Analyzer maintenance sheets revealed no written documentation of daily quality control maintenance, monthly maintenance, six month maintenance and calibration maintenance were filled in from Oct 2023 to November 2024 by testing personnel with dates. Review of Medonic M-Series Manual read, " All maintenance should be documented (a maintenance log is recommended) and the documentation saved for a minimum of 2 years. Review of General maintenance policy signed by the laboratory director on 8/1/2023 read "instrument maintenance, function checks and corrective actions are documented with date and initials on the instrument log. On 11/20/2024 at 2:34 PM, the physician assistant confirmed M-Series Hematology Analyzer maintenance sheets were not filled out October 2023 to November 2024.

**D5447**

**CONTROL PROCEDURES**  
CFR(s): 493.1256(d)(3)(i)(g)

Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each quantitative procedure, include two control materials of different concentrations; (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:  
Based on record review and interview, the laboratory failed to perform two levels of controls on i-STAT CHEM8+ for 1(patient A) out 1 patient reviewed on 4/25/2023. Findings include: Review of i-STAT CHEM8+ Quality control log revealed no controls were run on 4/25/2023. Review of Patient log revealed the following: Patient A was tested on 4/25/2023 with the i-STAT CHEM8+ for Sodium (Na), Potassium (K.), Chloride (Cl), total carbon dioxide content (TCO2), Ionized Calcium (iCa), Glucose (Glu), Urea Nitrogen)/Urea, Creatinine (Crea)Hematocrit (Hct) and Hemoglobin\* (Hgb). Review of Quality Control and assessment read, "Chem8+ (Abbott I-Stat) 1. External QC runs two levels of external controls at the beginning of each day of operation prior to running patient samples after maintenance has been performed." On 11/20/2024 at 2:34 PM, the physician assistant confirmed two levels of control on i-STAT CHEM8+ were not run for patient A on 4/25/2023.