

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 34D2111957	(X3) Date Survey Completed 10/09/2025
Name of Provider or Supplier Ecu Health Multispecialty Clinic Belhaven	Street Address, City, State 598 West Old County Road, Belhaven, NC	
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
D5413	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p> <p>(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.</p> <p>This STANDARD is not met as evidenced by: Based on review of the operator's manual and user's manual, review of 2024 and 2025 temperature logs, and interview with the Quality Assurance (QA) Manager on 10/09/2025, the laboratory failed to establish a room temperature range consistent with manufacturer requirements. Findings: Review of the "Medica ezra Operator's Manual" section 10.20 revealed, "...EasyRA...operated...15-30C (59-86F)..." Review of the "Medonic M series User's Manual" section 11.2 revealed, "...64 - 90F (18 - 32C)..." Review of laboratory temperature logs for 2024 and 2025 revealed, "...Temperatures... Room...55-85..." The laboratory does not meet manufacture required ranges for the Medica ezra 15-30C (59-86F) and the Medonic 64 - 90F (18 - 32C). During interview at approximately 3:41 p.m., the QA Manger confirmed incorrect temperature range listed on the temperature logs and the temperature range is missing the unit of measurement in degrees Fahrenheit.</p>