

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 34D0713730	(X3) Date Survey Completed 06/11/2024
Name of Provider or Supplier Ecu Health Women's Care - Washington	Street Address, City, State 1204 Brown St, Washington, 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
D5437	<p>CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(a)</p> <p>Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (2) Using the criteria verified or established by the laboratory as specified in 493.1253(b) (3)-- (2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification.</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory procedure, lack of documentation of 2022, 2023 and 2024 chemistry calibration records and interview with laboratory manager 6/11/24, the laboratory failed to document calibrations for the testing performed on the Medica Easy RA chemistry analyzer since testing began in November of 2022, a period of approximately 19 months. Findings: Review of laboratory policy, "Quality Control and Calibration Procedure", revealed "Documentation...All calibrations must be documented as to when they were performed, who performed them, and whether they were acceptable or unacceptable.". Review of Medica Easy RA calibration records for 2022, 2023 and 2024 revealed no documentation of calibrations since testing began in November of 2022. Interview with laboratory manager at approximately 11:45 a.m. confirmed the laboratory had no documentation of the calibrations performed on the Medica Easy RA chemistry analyzer. They stated the instrument will not allow you to perform testing if calibrations are needed and they did not think documentation that calibration was performed would be necessary.</p>