

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 34D2210862	(X3) Date Survey Completed 09/15/2025
Name of Provider or Supplier Reproductive Specialists Of The Carolinas	Street Address, City, State 1918 Randolph Road, Suite 410, Charlotte, 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
D5439	<p>CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b)</p> <p>(b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3)-- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification.</p> <p>This STANDARD is not met as evidenced by: Based on review of calibration verification records for the Cobas e411 analyzer, review of the Cobas e411 Calibration Verification policy, and interview with testing personnel (TP1), the laboratory failed to perform calibration verification within six months of the previous calibration. Findings: Review of calibration verification records revealed calibration verifications performed on 2/17/24, 8/2/24, and 6/6/25. The calibration verification was due in February 2025. The laboratories Cobas e411 Calibration Verification policy states, "This three/five-point calibration needs to be</p>

performed once every six months." During an interview at approximately 1:25 p.m., TP1 confirmed the Validate calibration verification material was ordered for June 2025 due to confusion with the dates.