

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 42D2118805	(X3) Date Survey Completed 04/17/2025
Name of Provider or Supplier Orthosc	Street Address, City, State 210 Village Center Boulevard, Myrtle Beach, SC	
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 onsite announced CLIA recertification survey was conducted on April 17, 2025, at the clinical laboratory of OrthoSC of Myrtle Beach by the South Carolina Department of Public Health's (SC DPH) Bureau of Nursing Homes and Medical Services. The laboratory was found to be out of compliance with 42 CFR Part 493, CLIA Requirements for Laboratories. Standard level deficiencies were identified during the recertification survey:
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p> <p>This STANDARD is not met as evidenced by: Based on records review, lack of documentation, and staff interview, the laboratory failed to follow its own employee competency policy to ensure annual assessments of employee competency for 1 of 1 personnel. Findings included: 1. Review of the employee competency policy and procedure reveals that the laboratory policy called for employee competency assessments to occur "Quarterly". 2. Review of competency documentation for Testing Personnel 1 (TP1) reveals competency assessments dated 03/24/22 and 10/13/22 with a hire date of 10/3/2019. 3. Review of employee competency documentation finds no evidence of initial, 6 months, or annual competencies conducted as required. 4. In an interview with TP1 on April 17, 2025 at 2:00pm in the laboratory office, the findings were confirmed.</p>