

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 42D0251505	(X3) Date Survey Completed 10/21/2024
Name of Provider or Supplier Musc Health Women's Health	Street Address, City, State 1590 Freedom Blvd Suite B, Florence, 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 October 29, 2024, at the clinical laboratory of MUSC Health OB/GYN of Florence by the South Carolina Department of Public Health's 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. The following is a list of STANDARD level deficiencies cited:
D5449	<p>CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(g)</p> <p>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 qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed.</p> <p>This STANDARD is not met as evidenced by: Based on laboratory document review, procedure review , and straff interview, the laboratory failed to include a negative and positive control for qualitative test procedure. Findings included: 1. The laboratory's procedure for Becton and Dickenson's Affrim VPIII test calls for a positive control only. 2. The laboratory's Quality Control Assessment procedure calls for a positive and negative controls for qualitative testing. 3. In an interview on 10/29/2024 at 1:00pm in the laboratory with the practice manager, the findings were confirmed.</p>