

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 42D2312438	(X3) Date Survey Completed 07/27/2026
Name of Provider or Supplier Lowcountry Oncology Associates, Llc-Mt Pleasant	Street Address, City, State 1300 Hospital Drive, Mt Pleasant, 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 announced onsite CLIA initial survey was conducted on July 27, 2026 at the laboratory of Lowcountry Oncology Associates of Mt. Pleasant by the South Carolina Department of Public Health (SC DPH) Bureau of Nursing Homes and Medical Services. The laboratory was found to be out of compliance with conditions of participation for the Clinical Laboratory Improvement Amendments (CLIA) of 1988 requirements found at 42 CFR Part 493. The following is a list of STANDARD LEVEL deficiencies cited as a result of the initial survey of July 27, 2026:
D2014	TESTING OF PROFICIENCY TESTING SAMPLES (b)(6) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. This STANDARD is not met as evidenced by: Based on records review, lack of documentation, and staff interview, the laboratory failed to provide documentation of review and oversight of the laboratory's proficiency testing (PT). Findings included: 1. A review of College of American Pathology (CAP) proficiency testing reveals the following: a. 2026 FH 16A score 100% b. 2026 FH 16B score 100% 2. The surveyor requested and the laboratory failed to provide reviewed and signed attestation sheets for 2 out of 2 events of PT testing. 3. In an interview on July 27, 2026 at 1:00pm in the laboratory office with the laboratory supervisor, the findings were confirmed.