Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	42D2312446	07/29/2026
Name of Provider or Supplier	**Street Address, City, State**	
Lowcountry Oncology Associates, Llc-West Ashley	1176 Sam Rittenberg Blvd, Charleston, 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 29, 2026, at the laboratory of Lowcountry Oncology Associates of West Ashley Charleston 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 29, 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 oversite of the laboratory's proficiemcy testing (PT). Findings included: 1. Review of the College of American Pathology (CAP) PT documentation reveals the laboratory performed PT testing for the non-waived moderately complex tesing of specialty Hematology. 2. The surveyor requested and the laboratory failed to provide signed and dated attestation forms for the following events: a. CAP 2026 Hematology 1st event b. CAP 2025 Hematology 1st event c. CAP 2025 Hematology 2nd event 3. In an interview on July 29, 2026 at 12:30pm in the laboratory office with the laboratory supervisor, the findings were confirmed.

D6013	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(ii) (e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method; and This STANDARD is not met as evidenced by: Based on direct observation , lack of documantation, and staff interview, the laboratory director failed to document review and approval of instrument installation and verification. Findings included: 1. In a tour of the laboratory on July 29, 2026 at 12:30pm, surveyor observed a Beckman Coulter DxH 520 in use. 2. Review of the Beckman Coulter verification data reveals a lack of review and approval of the DxH 520 installation and verification by the LD. 3. In a interview on July 29, 2026 at 12: 30pm in the laboratory office with the laboratory supervisor, the findings were confirmed.
D6046	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8) (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. The procedures for evaluation of the competency of the staff must include, but are not limited to-- This STANDARD is not met as evidenced by: Based on records review and staff interview, the laboratory director failed to use the CMS approved 6 standards of competency assessment in the evaluation of employee competency. Findings included: 1. Review of competency assessment forms reveals a lack of use of the 6 CMS approved competency standards as follows: a. Direct observation of routine patient testing performance. b. Monitoring the recording and reporting of test results. c. Review of intermediate test results or worksheets, quality control records, proficiency testing reults, and preventive maintenance records. d. Direct observation of performance of instrument maintenance and function checks. e. Assessment of test performance through testing of previously analyzed specimens. f. Assessment of problem solving skillls. 2. In an interview on July 29, 2026 at 12:30pm in the laboratory office with the laboratory supervisor, the findings were confirmed.