Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	42D2312440	07/27/2026
Name of Provider or Supplier	**Street Address, City, State**	
Lowcountry Oncology Associates,Llc-N Charleston	9313 Medical Plaza Dr, North 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 onsite announced CLIA initial survey was conducted at Lowcountry Oncology Associates, LLC on July 27, 2026, by the South Carolina Department of Public Health (SC DPH), Bureau of Nursing Homes and Medical Services. The facility was found to be out of compliance with Conditions of Participation for Clinical Laboratory Improvement Amendment (CLIA) of 1988 requirements found at 42 CFR Part 493. The following STANDARD LEVEL DEFICINCIES were found to be out of compliance as a result of the initial survey on July 27, 2026:
D1001	CERTIFICATE OF WAIVER TESTS CFR(s): 493.15(e) 493.15(e) Laboratories eligible for a certificate of waiver must-- (1) Follow manufacturers' instructions for performing the test; and (2) Meet the requirements in subpart B, Certificate of Waiver, of this part. This STANDARD is not met as evidenced by: Based on direct observation, lack of documentation, and staff interview, the laboratory failed to follow manufacturer's instructions as it relates to storage, handling of reagents used for waived testing for 4 out of 4 test(s) performed in the past 3 years (2024, 2025, 2026). Findings included: 1. The surveyor toured the laboratory on July 27, 2026, at 4:39 pm and directly observed the following kits/reagents in use: a. Urispec 10SG Henry Schein b. Accutest Valupak hCG Urine Pregnancy Test Cassette (CLIA Waived) c. 7 pouches, Piccolo Xpress chemistry analyzer, ABAXIS, Lot#6211BA6 expire 2027-5-18 d. Hemosure iFOB (CLIA Waived) testing 2. A review of storage and stability instructions for the following reagents reveal specified temperature and expirations after placing at room temperature and/or opening the container/pouch. The following reagents lack documentation of open date and/or times: a. Urispec 10SG Henry Schein, once canister has been opened, the remaining strips are stable for up to 3 months, 1 unsealed container lack documentation of open date and times. b. Piccolo Xpress discs can remain in its sealed pouch at room

	temperature for a cumulative period of 48 hours. Pouches lack documentation of when it was placed at room temperature. 3. A review of the directions for use reveals specified time requirements for the following procedures. The laboratory lacks documentation of timer verification. a. Accutest VALUPAK Hcg Urine Pregnancy Test Cassette b. Hemosure iFOB (CLIA Waived) 4. In an interview on July 27, 2026, at 5:15 pm in the office with the technical consultant TC the above findings were confirmed.
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) (b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods. This STANDARD is not met as evidenced by: Based on record review, lack of documentation, and staff interview, the laboratory director (LD) and testing personnel (TP) failed to attest to the routine integration of the samples into the patient workload using the laboratory's routine methods for 2 out of 4 Events reviewed. Findings included: 1. Review of College of American Pathology (CAP) records reveals proficiency testing (PT) was enrolled and performed twice a year for 2025 and 2026. 2. The surveyor requested but the laboratory failed to provide attestation sheets for the following events: a. FH16-A 2026, ran 1/21/2026, reviewed on 03/18/2026 by LD but no attestation sheet. b. FH16-B 2026, reviewed on 6/4/2026 by LD, no attestation sheet. 3. In an interview on July 27, 2026, at 5:15 pm wth TC in the office, the above findings were confirmed.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) (b) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (b)(1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (b)(1)(i)(A) Accuracy. (b)(1)(i)(B) Precision. (b)(1)(i)(C) Reportable range of test results for the test system. (b)(1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on record review, lack of documentation, and staff interview, the laboratory failed to provide a complete report for performance verification to adequately meet the clients' needs as determined by the laboratory director/clinical consultant. The laboratory is responsible for verifying the manufacturer's analytical claims before initiating patient testing. This may be accomplished by the laboratory testing "known" samples. Findings included: 1. A review of verification of performance reveals accuracy but no complete summary of the data included in the binder. Reportable range and/or reference intervals/range were not available on the day of survey. 2. The surveyor requested and the laboratory failed to provide other pertinent performance characteristics of the method and/or the laboratory director's approval of adequate verification procedures performed. 3. In an interview on July 27, 2026, at 5:15 pm with TC in the office, the above findings were confirmed.

D5433	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(1) (b)(1)(i) Establish a maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (b)(1)(ii) Perform and document the maintenance activities specified in paragraph b(1)(i) of this section. This STANDARD is not met as evidenced by: Based on direct observation, lack of documentation, and staff interviews, the laboratory failed to establish a maintenance protocol that ensures equipment, instrument, and test system performance were maintained for 2 out 2 years reviewed (2025, 2026). Findings included: 1. The surveyor toured the laboratory on July 27, 2026, at 4:39 pm and directly observed 2 centrifuges being used to process blood specimens. 2. The surveyor requested but the laboratory failed to provide maintenance records on 2 out of 2 pieces of equipment used to process blood specimens. 3. In an interview on July 27, 2026, at 5:15 pm with TC in the office, the above findings were confirmed.
D5775	COMPARISON OF TEST RESULTS CFR(s): 493.1281(a)(c) (a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. This STANDARD is not met as evidenced by: Based on record review, lack of documentation, and staff interview, the laboratory failed to compare test results from other Lowcountry Oncology Associates that perform the same test at least twice a year for the 2 out 2 years evaluated (2025 and 2026). Findings included: 1. Review of policy and procedures titled "Comparison of Test Results; Reference 493.1281 & 493.1236" reveals the following statement: c) The laboratory must document all test result comparison activities. 2. The surveyor requested documentation of the hematology (moderately complex) system that the laboratory uses to evaluate the same tests performed at multiple locations, but the laboratory provided no documentation on the day of inspection. 3. In an interview on July 27, 2026, at 5:15 pm with TC in the office, the above findings were confirmed.
D6032	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(14) (e)(14) Specify, in writing, the responsibilities and duties of each consultant and each person, engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or results reporting, and whether consultant or director review is required prior to reporting patient test results. This STANDARD is not met as evidenced by:

	Based on records reviewed, lack of documentation, and staff interview the laboratory director failed to specify in writing the responsibilities and duties of each person engaged in the performance of preanalytical, analytical and postanalytical phases of testing and identify which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or results reporting and whether consultant or director review is required prior to reporting patient test results. Assigned positions (TC and TP) must be current. Findings included: 1. Review of CMS 209 reveals the following personnel: a. 1 laboratory director/Clinical Consultant (LD/CC) b. 1 Technical Consultant (TC) c. 12 Testing Personnel (TP) 2. The surveyor requested but the laboratory failed to provide written responsibilities and duties of each person involved in all phases of the testing process. No documentation was available on the day of survey with the written responsibilities of the following assigned positions: a. TC b. TP 3. In an interview on July 27, 2026, at 5:15 pm with TC in the office, the above 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 record review, lack of documentation, and staff interview, the laboratory failed to provide competency records for the new moderately complex testing in 2025 for 6 out of 12 testing personnel (TP). Findings included: 1. Review of CMS 209 personnel report reveals 12 TP for moderately complex testing performed. a. TP1 b. TP2 c. TP3 d. TP4 e. TP5 f. TP6 g. TP7 h. TP8 i. TP9 j. TP10 k. TP11 l. TP12 2. Review of training and/or competency records reveals 6 out of 12 TP lacks 2025 annual competency: a. TP1 b. TP3 c. TP4 d. TP5 e. TP7 f. TP12 3. In an interview on July 27, 2026, at 5:15 pm with TC in the office, the above findings were confirmed.