Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	42D1037609	03/12/2026
Name of Provider or Supplier	**Street Address, City, State**	
Carolina Dermatology	933 St Andrews 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 CLIA onsite recertification survey was conducted at the Carolina Dermatology Laboratory on March 12, 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 Medicare Condition 42 CFR Part 493. CLIA laboratory requirements. The following STANDARD LEVEL DEFICINCIES were found to be out of compliance:
D5219	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(2) (c)(2) Any test or procedure listed in subpart I of this part for which compatible proficiency testing samples are not offered by a CMS-approved proficiency testing program. This STANDARD is not met as evidenced by: Based on reviewed records, lack of documentation, and staff interview, the laboratory failed to establish and/or document laboratory tests accuracy for which compatible proficiency testing samples are not offered by a CMS-approved proficiency testing program for 1 out of 2 years reviewed (2024 and 2025). Findings included: 1. A review of 2025 professional evaluation records for laboratory director reveals a lack of documentation of verification of accuracy for unregulated testing program for histology high complexity testing. 2. The laboratory lacks sufficient documentation of blind testing/assessment of histology slides read by laboratory director and another peer professional for 2025. 3. In an interview on March 12, 2026, at 3:00 pm in the conference room/breakroom with consultant and testing personnel the above findings were confirmed.
D5291	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(a)

	The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236. This STANDARD is not met as evidenced by: Based on records review, lack of documentation, and staff interview, the laboratory failed to establish and/or follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236 for 2 out of 2 years reviewed (2024 and 2025). Findings included: 1. A review of policy and procedures titled Quality Assurance procedures reveals a. Once labs are received from outside reference labs if any errors occur, a log report will be documented. b. Quarterly review of 10 patients verifying accuracy and completeness No documentation was available on the day of inspection. 2. In an interview on March 12, 2026, at 3:00 pm in the conference room/breakroom with consultant and testing personnel the above findings were confirmed.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) (d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on direct observation, lack of documentation, and staff interview, the laboratory failed to ensure test systems and/or equipment being used to process histology tissue samples did not exceed their expiration or are of substandard quality for the 2 out of 2 years reviewed (2024 and 2025). Findings included: 1. During a tour of the laboratory on March 12, 2026, at 2:45 pm the surveyor observed: a. ThermoPro thermometer expired 11/31/2023 b. Mueller microwave oven for drying slides, lack maintenance sticker. 2. Surveyor request and the laboratory failed to provide verification of performance documentation on equipment used to process histology tissue. 3. In an interview on March 12, 2026, at 3:00 pm in the conference room/breakroom with consultant and testing personnel the above findings were confirmed.
D6005	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(c) (c) The laboratory director must: (c)(1) Be onsite at least once every 6 months, with at least 4 months between the minimum two on-site visits. Laboratory directors may elect to be on-site more frequently and must continue to be accessible to the laboratory to provide telephone or electronic consultation as needed; and (c)(2) Provide documentation of these visits, including evidence of performing activities that are part of the laboratory director responsibilities. This STANDARD is not met as evidenced by: Based on reviewed records, lack of documentation, and staff interview, the laboratory director failed to provide on-site regular interactions between him/herself and the lab

	for 2 out of 2 years reviewed (2024 and 2025). Findings included: 1. A review of laboratory records reveals the lacks documentation of the laboratory director's on-site visits demonstrating the laboratory's continuous compliance with the assessment of overall quality assessment of laboratory operations. 2. The surveyor request and the laboratory failed to provide documentation of the laboratory director's documentation signed logs, minutes, or notes of observations. 3. In an interview on March 12, 2026, at 3:00 pm in the conference room/breakroom with consultant and testing personnel the above findings were confirmed.