Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	42D2240472	07/13/2026
Name of Provider or Supplier	**Street Address, City, State**	
Charleston Dermatology	3508 S Live Oak Drive, Moncks Corner, 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 Charleston Dermatology on July 13, 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 13, 2026:
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 policies and procedures reviewed, 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 3 out of 3 years reviewed (2024, 2025, and 2026). Findings included: 1. Review of QC/QA Charleston Dermatology, Berkely Mohs Lab records reveal documentation of task performed for high complexity testing: a. Cryostat temperature recorded b. Cryostat cleaned c. Eyewash pluming checked d. HE Stain changed e. HE Stain acceptance 2. The surveyor requested and the laboratory failed to provide what quality indicators would be monitored, how frequently, and threshold of acceptance for each key performance indicator. "Mohs Quality Assessment Procedure states a review of the Mohs log against the surgery schedule for accuracy and completion. In addition, remedial action would be taken." On the day

	of survey, the laboratory lacks documentation of any investigation(s),or identification (s) of problems, and resolution of problems, followed by development of any policies that will prevent recurrence. 3. In an interview on July 13, 2026, at 2:51 pm with staff the above findings were confirmed.
D5293	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(b)(c) (b) The general laboratory systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of general laboratory systems quality assessment reviews with appropriate staff. (c) The laboratory must document all general laboratory systems quality assessment activities. This STANDARD is not met as evidenced by: Based on policies and procedures reviewed, lack of documentation, and staff interview, the laboratory failed to establish and/or follow written policies and procedures for an ongoing assessment including a review of the effectiveness of the corrective action taken to resolve problems, revisions of policies and procedures necessary to prevent recurrence of problems, and discussion of general laboratory systems quality assessment reviews with appropriate staff for 3 out of 3 years reviewed (2024, 2025, and 2026). Findings included: 1. Review of "QC/QA Charleston Dermatology, Berkely Mohs Lab" records reveal documentation of task performed for high complexity testing: a. Cryostat temperature recorded b. Cryostat cleaned c. Eyewash pluming checked d. HE Stain changed e. HE Stain acceptance 2. The surveyor requested quality assurance documentation of the laboratory director's review and communication with the laboratory personnel and other staff, clients, etc. as appropriate but the laboratory failed to provide the documentation of review and/or corrective action(s) taken with any identified problem(s). 3. In an interview on July 13, 2026, at 2:51 pm with staff 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 that equipment had not exceeded their expiration date, has deteriorated, or are of substandard quality for 3 out of 3 years reviewed (2024, 2025, and 2026). Findings included: 1. During a tour of the laboratory on July 13, 2026, at 2: 33 pm the surveyor observed the following pieces of equipment: a. Microscope b. Thermometer c. Cryostat 3 out of 3 pieces of equipment lack maintenance stickers. 2. The surveyor requested and the laboratory failed to provide accuracy verification of equipment used for high complexity testing. No documentation was available on the day of the survey. 3. In an interview on July 13, 2026, at 2:51 pm with staff 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 document verification of performance specifications. As required 493.1253 the laboratory must verify or establish performance specifications for high complexity tests introduced into the laboratory before reporting patient test results. The verification of method performance should provide evidence that the accuracy, precision, and reportable range of the procedure are adequate to meet the clients' needs, as determined by the laboratory director and clinical consultant. Findings included: 1. Review of CMS 116 application reveals high complexity testing of Mohs Surgery being performed. 2. The surveyor requested and the laboratory failed to provide verification for 3 out of 3 pieces of equipment used in the high complexity testing of Mohs Surgery. a. Microscope b. Thermometer c. Cryostat No documentation was available on the day of survey. 3. In an interview on July 13, 2026, at 2:51 pm with staff the above findings were confirmed.