Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	42D2240128	08/04/2026
Name of Provider or Supplier	**Street Address, City, State**	
Germain Dermatology	602 North Main Street, Summerville, 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 recertification survey was conducted on August 4, 2026 at the laboratory of Germain Dermatology of Summerville 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 Amendents (CLIA) of 1988 requirement found at 42 CFR Part 493. The following is a list of STANDARD LEVEL deficiencies cited as a result of the August 4, 2026 recertification survey:
D6029	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(11) (e)(11) Ensure that prior to testing patients specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results; This STANDARD is not met as evidenced by: Based on records review, employee competency policy, and staff interview, the technical supervisor (TS) failed to ensure the training and initial competency assessments of new hires. Findings included: 1. A review of policy and procedure entitled "Personnel Competency Testing" reveals competency evaluations to be completed initially, at 6 months, and annually therafter. 2. The surveyor requested but the laboratory failed to provide employee competency records for 1 out of 1 employee. 3. In an interview on August 4, 2026 at 12:00pm with the TS in the laboratory office, the findings were confirmed.
D6053	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) (b)(9) Evaluating and documenting the performance of individuals responsible for

	moderate complexity testing at least semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: Based on records review, employee competency policy, and staff interview, the technical supervisor (TS) failed to ensure the training and 6 months competency assessment of new hires. Findings included: 1. A review of "Personnel Competency Assessment" policy and procedure reveals no effective date for training and competency of all testing personel will be ensured prior to testing patient specimens. 2. The surveyor requested training and competency assessment records, but the laboratory failed to provide completed records for testing personnel. No records were available on the day of survey. 4. In an interview on August 4, 2026 at 12:00pm with the TS in the laboratory office, the findings were confirmed.