Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	42D2282632	05/20/2025
Name of Provider or Supplier	**Street Address, City, State**	
Grand Strand Dermatology	7410 Highway 707, Myrtle Beach, 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 initial certification survey was conducted at Grand Strand Dermatology by South Carolina Department of Public Health (SC DPH) and Bureau of Nursing Homes and Medical Services on May 20, 2025. The facility was found to be out of compliance with the Medicare Condition at 42 CFR Part 493 Laboratory Requirements. The following is a list of STANDARD LEVEL deficiencies cited as a result of May 20, 2025, initial survey.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on record review, lack of documentation, and staff interview, the laboratory failed to establish and follow written policies and procedures to assess the competency for 4 of 4 high complex testing personnel listed on the CMS-209 for 3 years reviewed (2023, 2024 and 2025). 1. Review of CMS 209 personnel report form reveals 2 clinical consultants (CC) and 2 testing personnels (TP). 2. The surveyor requested and the laboratory failed to provide written policies and procedures to describe the laboratory's process for assessing the competency of 2 of 2 testing personnels and 2 of 2 clinical consultants. a. TP1 b. TP2 c. CC1 d. CC2 No competency documents available day of survey for any employees. 3. In an interview on May 20, 2025, at 4: 04 pm in the conference room with testing personnel, the above findings were confirmed.
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 records review, lack of documentation, and staff interview, the laboratory failed to provide documentation of the laboratory verifying the accuracy of provider performed microscopy (PPM) and the reading of histopathology slides twice per year for 2 of 2 years reviewed (2024 and 2025). Findings included: 1. Review of CMS 116 application and lab director's form reveals the providers performs microscopic examination of wet mounts and potassium hydroxide (KOH) for the presence or absence of bacteria, fungi, parasites, and human cellular elements. 2. The surveyor requested and laboratory failed to provide competency documentation on day of survey May 20, 2025, at 4:04 pm for 3 of 3 providers performing PPMs and the reading of histopathology slides. 3. In an interview on May 20, 2025, at 4:04 pm in the conference room with TP1 and TP2, 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 policies and procedures, lack of documentation and staff interview, the laboratory failed to establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in general laboratory systems requirements as specified at 493.1231 through 493.1236. Findings included: 1. Review of policies and procedures reveals the laboratory failed to establish and follow written policies and procedures for personnel competency, and proficiency testing performance. 2. On May 20, 2025, at 4:04 pm, day of survey no quality management plan was available for review. 3. In an interview on May 20, 2025, at 4:404 pm in the conference room with TP1 and TP2, the above findings were confirmed.
D5601	HISTOPATHOLOGY CFR(s): 493.1273(a)(f) (a) As specified in 493.1256(e)(3), fluorescent and immunohistochemical stains must be checked for positive and negative reactivity each time of use. For all other differential or special stains, a control slide of known reactivity must be stained with each patient slide or group of patient slides. Reactions of the control slide with each special stain must be documented. This STANDARD is not met as evidenced by: Based on policies and procedures reviewed, patient's records reviewed, and staff interview, the laboratory failed to document the reaction for each time a special stain was reported as required 493.1273. Findings included: 1. Review of procedure titled

	"Periodic Acid-Schiff's Stain (P.A.S) Kit Procedure" and "Periodic Acid-Schiff Stain for Fungus Quality Control" reveals the reactions for the special stain as green background for tissue and pink to red magenta for fungus presence. 2. Review of patient report(s) reveals the staining reaction of known postive controls are not documented on final report or on quality assurance form. a. Patient # 24-1006-A b. Patient # 24-8151-A No documentation of special stain reactions PAS control was available on day of survey. 3. In an interview on May 20, 2025, at 4:04 pm in the conference room with TP1and TP2, the above findings were confirmed.
D6084	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(2) provide a safe environment in which employees are protected from physical, chemical, and biological hazards; This STANDARD is not met as evidenced by: Based on lack of documentation and staff interview the laboratory failed to monitor the environment to ensure employees are protected from physical, chemical (formalin and Xylene), and biological hazards for 2 of 2 years reviewed (2024 and 2025). Findings included: 1. Review of CMS 116 application identifies the specialty of histopathology. 2. Review of records lacks documentation of formalin exposure for 2 of 2 years reviewed (2024 and 2025). 3. In an interview on May 20, 2025, at 6:00 pm in the laboratory with testing personnel, the above finding was confirmed.
D6087	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(3)(iii) (e)(3)(iii) Laboratory personnel are performing the test methods as required for accurate and reliable results; This STANDARD is not met as evidenced by: Based on records reviewed, lack of documentation and staff interview the laboratory director failed to ensure laboratory personnel are performing test methods as required for accurate and reliable results. Reference D5219, D6120, D6127, D6128.
D6107	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(15) (e)(15) Specify, in writing, the responsibilities and duties of each consultant and each supervisor, as well as 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 result reporting and whether supervisory or director review is required prior to reporting patient test results. This STANDARD is not met as evidenced by: Based on records review, lack of policies and procedures and staff interview, the laboratory failed to specify in writing the responsibilities and duties of the clinical consultant and testing personnel as well as each person engaged in the performance of preanalytical, analytic, and postanalytical 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 result reporting and whether supervisory or director review is required 493.1413 (b) (7) (8) prior to reporting test results. Findings included: 1. Review of CMS 209 personnel report form reveal 1 laboratory director (LD), 2 clinical consultant(s) (CC), and 2 testing personnel (s) (TP). 2. Review of policies and procedures for high complex testing laboratory reveal a lack of written duties/responsibilities for each person involved in all phases of the testing process on the day of survey. 3. In an interview on May 20, 2025, at 4:04 pm with TP1 and TP2 the above findings were confirmed.
D6120	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(7)(8) (b)(7) Identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed; (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. This STANDARD is not met as evidenced by: Based on records review and staff interview, the laboratory director/technical supervisor failed to provide documentation of initial training for high complexity testing as required 493.1451 for 2 of 2 TPs reviewed. Findings included: 1. Review of CMS 209 personnel report form list 1TS and 2TP. 2. A review of records reveals the laboratory lacked documentation of initial training for TP1 and TP2. 3. An interview was conducted with the testing personnel on May 20, 2025, at 4:04 pm in the conference room the above findings were confirmed.
D6127	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(9) (b)(9) Evaluating and documenting the performance of individuals responsible for high 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, lack of documentation and staff interviews, the laboratory director/technical supervisor failed to evaluate and document performance of high complexity testing personnel at least semiannually during the first year of hire and before the individual(s) test patients' specimens for 2 out 2 testing personnel (TP) in the 3 of 3 years reviewed (2023, 2024 and 2025). Findings included: 1. Review of CMS 209 personnel report reveals 2 TP identified during the initial survey. 2. Review of TP1 and TP2 personnel forms reveals lack of documentation as initial and or semi-annual competency. 3. In an interview with TP1 and TP2 on May 20,2025 at 4:04 pm in the conference room, the above finding confirmed.
D6128	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(9) (b)(9) Thereafter, evaluations must be performed at least annually unless test methodology or instrumentation changes, in which case, prior to reporting patient test

	results, the individuals performance must be reevaluated to include the use of the new test methodology or instrumentation. This STANDARD is not met as evidenced by: Based on records review, lack of documentation and staff interviews, the laboratory director/technical supervisor failed to evaluate and document performance of high complexity testing personnel at least annually during the first year of hire and before the individual(s) test patients' specimens for 2 out 2 (TP) in 3 of 3 years reviewed (2023, 2024 and 2025) . Findings included: 4. Review of CMS 209 personnel report reveals 2 TP identified during the initial survey. 5. Review of TP1 and TP2 personnel forms reveals lack of documentation as annual competency. 6. In an interview with TP1 and TP2 on May 20,2025 at 4:04 pm in the conference room, the above finding confirmed.