Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	42D1107252	03/19/2026
Name of Provider or Supplier	**Street Address, City, State**	
May River Dermatology	7 Arley Way, Suite 101, Bluffton, 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 May River Dermatology on March 19, 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:
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 reviews, lack of documentation, and staff interview, the laboratory failed to establish and follow written policies and procedures to assess employees and consultants competencies for 2 out of 2 years reviewed (2025 and 2026). Findings included: 1. A review of CMS 209 Laboratory Personnel Report (CLIA) record reveals: a. 1 director=D b. 1 clinical consultant=CC c. 2 technical supervisors=TS d. 3 general supervisors=GS e. 6 testing personnel=TP 2. The surveyor requested and the laboratory failed to provide written policies and procedures to assess competency based on the positions required for high complexity testing. All delegated positions must have a written policy documenting how the staff will be evaluated for the position that he/she has been delegated for. No documentation was available for CC, TS, and GS on the day of inspection. 3. In an interview on March 19, 2026, at 4:50 pm in the office with office manager and testing personnel (TP5), 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 record 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. Findings included: 1. A review of policies and procedures reveals the laboratory failed to establish and/or follow polices concerning communication and documenting when problems occur for personnel, equipment, and/or reagents. 2. A review of problem with equipment documented that company came and repaired it, however no statement or documentation of verification of performance to document that the equipment is now functioning properly. 3. In an interview on March 19, 2026, at 4:50 pm in the office with office manager and testing personnel (TP5), the above findings were confirmed.
D6079	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(a)(b) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, record and report test results promptly, accurately and proficiently, and for assuring compliance with the applicable regulations. (a) The laboratory director, if qualified, may perform the duties of the technical supervisor, clinical consultant, general supervisor, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications under 493.1447, 493.1453, 493.1459, and 493.1487 respectively. (b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed. This STANDARD is not met as evidenced by: Based on record reviewed, lack of documentation, and staff interview, the laboratory director failed to fulfill the responsibilities for overall operation and administration of the laboratory for 2 out of 2 years reviewed (2025, 2026). Refer D5209, D5291, D6080
D6080	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(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 records review, lack of documentation, and staff interview, the laboratory director failed to provide documentation of onsite visit at least once every 6 months, with at least 4 months between the minimum two on-site visits per year for 2 out of 2 years reviewed (2025 and 2026). Findings included: 1. A review of policies and procedures, lack of written position responsibilities, and lack of professional proficiency documentation reveals a lack of evidence of on-site oversight activities to monitor continuous compliance with current laws and regulations. 2. A review of proficiency testing for GS 3 reveals lack of documentation for 2 years reviewed (2025 and 2026). 3. In an interview on March 19, 2026, at 4:50 pm in the office with office manager and testing personnel (TP5), the above findings were confirmed.
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 record review, lack of documentation, and staff interview, the laboratory director failed to document the responsibilities and duties of the clinical consultant, each supervisor, and each person involved in all phases of the testing process. The list of assigned duties must be current. 2 years reviewed (2025 and 2026). Findings included: 1. A review of CMS 209 laboratory personnel report (CLIA) reveals 1 clinical consultant(CC), 2 technical supervisors(TS), 3 general supervisors (GS), 6 testing personnel (TP). 2. Surveyor requested written responsibilities of CC and TS, and the laboratory failed to provide written documentation of delegated responsibilities for high complexity testing being performed. No documentation available on the day of inspection. 3. In an interview on March 19, 2026, at 4:50 pm in the office with office manager and testing personnel (TP5), the above findings were confirmed.
D6112	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451 The technical supervisor is responsible for the technical and scientific oversight of the laboratory. The technical supervisor is not required to be on site at all times testing is performed; however, he or she must be available to the laboratory on an as needed basis to provide supervision as specified in (a) of this section. This STANDARD is not met as evidenced by: Based on record review, lack of documentation, and staff interview, the laboratory director failed to provide documentation of training for technical supervisor and general supervisor which the technical supervisor is responsible for testing personnel performance as required 493.1451. Findings included: 1. A review of CMS 209 Laboratory Personnel Report (CLIA) reveals: a. 1 director=D b. 1 clinical

	consultant=CC c. 2 technical supervisors=TS d. 3 general supervisors=GS e. 6 testing personnel=TP 2. The surveyor requested and the laboratory failed to provide documentation of training and competency based on the positions required for high complexity testing. All delegated positions must have training and competency documented for the position that he/she has been delegated for. No documentation was available for CC, TS, and GS on the day of inspection. 3. In an interview on March 19, 2026, at 4:50 pm in the office with office manager and testing personnel (TP5), 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 record review, lack of documentation, and staff interview, the TS/GS failed to provide documentation for 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 as required 493.1451(b)(8). Findings included: 1. A review of competency records reveals documents signed by GS2. 2. The surveyor requested and the laboratory failed to provide competency documents for the following TP: a. TP1, 2025 and 2026 b. TP6, 2025 and 2026 3. In an interview on March 19, 2026, at 4:50 pm in the office with office manager and testing personnel (TP5), the above findings were confirmed.