Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	42D2289016	06/06/2025
Name of Provider or Supplier	**Street Address, City, State**	
Reforme Dermatology And Aestetics, Llc	302 Wings Way, Suite 303, Mount Pleasant, 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 survey was conducted at Reforme Dermatology and Aesthetics, LLC by South Carolina Department of Public Health (SC DPH) and Bureau of Nursing Homes and Medical Services on June 6, 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 June 6, 2025, certification 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 employee(s) as required 493.1445 for 3 out of 3 years reviewed (2023, 2024,and 2025). Findings included: 1. Review of CMS 209 personnel report reveal 2 testing personnel (TP) for high complexity testing. 2. The surveyor requested and the laboratory failed to provide policies and procedures to assess employee(s) as required 493.1445 for high complexity testing. 3. In an interview on June 6, 2025, at 3:35 pm in the breakroom with the laboratory director and staff member, 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 review, lack of documentation, and staff interview, the laboratory failed to monitor, assess, and when indicated, correct problems identified in the general laboratory systems requirements as specified in 493.1231 through 493.1236 for the 3 out of 3 years reviewed (2023, 2024, and 2025). Findings included: 1. Review of policy and procedure titled "Quality Assessment Plan" stated "On a quarterly basis the Histotechnician or Director of Laboratory Operations will review 10 percent of cases done during the previous quarter. This process will include pulling the patients' charts, the Mohs log, and slides. They will be checked to make sure that the op-report, map, Mohs log and slides are accurate. If there are any discrepancies it will be noted on the Quarterly QA form and corrective action will be taken to prevent this from happening again." 2. The surveyor requested and the laboratory failed to provide documentation of any monitoring and/or assessing the quality of high complexity testing being performed for 3 out of 3 years reviewed (2023, 2024, and 2025). 3. Review of records reveal the laboratory lack documentation for 2023 proficiency testing in reading pathology slides 5 out of 5 months reviewed for 2023. 4. Review of records reveal lack of acceptable documentation for twice-annual proficiency testing as required 493.1236 for 2024 and 2025. On copying paper, a date was provided without traceable patient information, without the provider's name of who evaluated the slide, no summary of results. 5. In an interview June 6, 2025, at 3: 15 pm in the breakroom with the LD and staff member, 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 direct observations, lack of documentation, and staff interview, the laboratory failed to verify the performance specifications of Cryostat instrumentation as required 493.1253. Findings included: 1. A tour of the laboratory was conducted on June 6, 2025, at 2:30 pm and the surveyor directly observed a Lecia DM1000 Cryostat. 2. The surveyor requested and the laboratory failed to provide documentation of validation/verification of performance studies done before the reporting of patient results. 3. In an interview on June 6, 2025, at 3:15 pm in the breakroom with the LD and staff member the above findings were confirmed.
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 reviewed, lack of documentation and staff interview, the laboratory failed to ensure prior to testing patients' specimens, all personnel have the appropriate training for the type and complexity of the services offered and can perform all testing operations reliably to provide and report accurate results for 2 out of 2 testing personnel. Findings included: 1. Review of CMS 209 personnel report reveals 2 TPs listed. 2. The surveyor requested and the laboratory failed to provide documentation of initial training performed for TPs involved in high complexity testing operations prior to testing patients' specimens. 3. In an interview on June 6, 2025, 3:15 pm in the breakroom with LD and staff member, the above findings were confirmed.
D6121	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(8)(i) The procedures for evaluation of the competency of the staff must include, but are not limited to-- (b)(8)(i) Direct observations of routine patient test performance, including patient preparation, if applicable, specimen handling, processing and testing; This STANDARD is not met as evidenced by: Based on records review, lack of documentation, and staff interview, the technical supervisor failed to evaluate staff for six competencies as it relates to high complexity testing for 2 out of 2 testing personnel (TP)as required 493.1451. Findings included: 1. Review of policies and procedures titled: a. "Quality Assessment Plan" under section IX. Personal Assessment stated "The Laboratory Director will use personal observation to perform an ongoing evaluation of all employees of the laboratory to ensure competence in job performance. b. "Laboratory Director Job Description" under responsibilities #7 states "Observes and assures laboratory personnel proficiency for all techniques. c. "Laboratory Director Job Description" under responsibilities #8 states "Provides annual reviews and performance standard evaluations for all laboratory personnel. 2. The surveyor requested and the laboratory failed to provide documentation of employee(s) competency for high complexity testing for 2 out of 2 TP for the 3 out of 3 years reviewed (2023, 2024, and 2025). 3. In an interview on June 6, 2025, at 3:15 pm in the breakroom with LD and staff member, the above findings were confirmed.