Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	42D2280316	04/24/2025
Name of Provider or Supplier	**Street Address, City, State**	
Purvis Dermatology	3001 Newcastle Loop, 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 survey was conducted at Purvis Dermatology on April 24, 2025 by South Carolina Department of Public Health (SC DPH). The facility was found to be out of compliance with the Medicare Condition at 42 CFR 493 CLIA Laboratory Requirements. The following is a list of Standard Level deficiencies cited as a result of the INTIAL CLIA survey on April 24, 2025.
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: Based on records review and staff interview, the laboratory lacked documentation for proficiency testing of test not listed under Subpart I to verify the accuracy of their procedure for 2 out of 3 years reviewed (2023, 2024, 2025). Findings include: 1. Records reviewed CMS 209 list two TP for high complexity testing (histopathology). 2. Records reviewed titled Purvis Dermatology KOH Log and MOHS PROFESSIONAL QUALITY ASSURANCE REPORT reveals the laboratory lacked documentation of proficiency evaluations for 2023 and 2024. 3. In an interview on April 24, 2025, at 2:05 pm in the breakroom with LD and 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 direct observation, records review and staff interview, the laboratory lacked documentation of verification of performance specifications as required 493.1253 for each nonwaived unmodified FDA-cleared or approved test system before reporting patient test results. Findings include: 1. A tour the laboratory on April 24, 2025, at 11: 45 am the surveyor directly observed a Lecia Cryostat. 2. Records review reveals, the laboratory lacked documentation of performance specifications for Lecia Cryostat instrumentation on day of survey. 3. In an interview on April 24, 2025, at 2:05 pm in the breakroom with LD and staff 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 and staff interview, the laboratory failed to provide documentation of initial training for high complexity testing as required 493.1451 for 2 of 3 testing personnel (TP) reviewed. Findings include: 1. Review of CMS 209 personnel report form list 1 TS and 3 TP. 2. A review of records reveals the laboratory lacked documentation of initial training for TP2 and TP3. 3. An interview was conducted with lab director and staff on April 24, 2025 @ 2:05 pm in the breakroom 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 record review and staff interview, the laboratory failed to evaluate and document the performance of individuals responsible for high complexity testing at least semiannually during the first year the individual test patient specimens for 2 of 3 TP. Findings include: 1. Review of CMS 209 personnel report form list1 TS and 3 TP . 2. A review of records reveals the laboratory lacked documentation of semiannual training for TP2 and TP3 hired 2023. 3. An interview was conducted with lab director and staff on April 24, 2025 @ 2:05 pm in the breakroom the above findings were 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 record review and staff interview, the laboratory failed to evaluate and document the performance of individuals responsible for high complexity testing at least annually during the first year the individual test patient specimens for 2 of 3 TP. Findings include: 1. Review of CMS 209 personnel report form list 1 TS and 3 TP. 2. A review of records reveals the laboratory lacked documentation of annual training for TP2 and TP3 hired 2023. 3. An interview was conducted with LD and staff on April 24, 2025 @ 2:05 pm in the breakroom the above findings were confirmed.