Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	42D2088479	07/20/2026
Name of Provider or Supplier	**Street Address, City, State**	
Palmetto Spine & Pain Care Consultant, Llc	4736 Highway 17 Bypass, 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 unannounced onsite CLIA recertification survey was conducted on July 20, 2026, at the laboratory of Palmetto Spine and Pain Care Consultants LLC of Myrtle Beach 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 Medicare condition 42 CFR Part 493, CLIA requirements for laboratories. The following is a list of Standard Level deficiencies cited as a result of the recertification survey of July 20, 2026:
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, American Proficiency Institute (API) test scores, and staff interview, the laboratory failed to successfully participate in a CMS approved proficiency testing (PT) program in 2 out of 4 PT events reviewed (2024, 2025). Following included: 1. Review of API PT results reveals the following: a. 2024 Chemistry 1st event score of 67% for Benzodiazepines b. 2025 Chemistry 1st event score of 0% for Benzodiazepines 2. Review of API Performance Review and Corrective Action form reveals a lack of documentation of a full investigation not limited to identifing the cause of the error and what was implemented to prevent reoccurance. 3. In an interview on July 20, 2026 at 1:00pm in the laboratory office with the program director, the findings were confirmed.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) (a) A written procedures manual for all tests, assays, and examinations performed by

	the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on records review and staff interview at the time of the survey, the laboratory failed to have a written procedure manual for all tests, assays, and examinations performed by the laboratory. Findings included: 1. Review of the CMS 116 form reveals testing performed by the laboratory including moderately complex urine benzodaizapine. 2. The surveyor requested the laboratory's procedure manual to review. No procedure manual was available on the day of survey. 3. In an interview on July 20,2026 at 1:00pm in the laboratory office with the practice manager, the findings were confirmed.
D6031	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(13) (e)(13) Ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process; and This STANDARD is not met as evidenced by: Based on lack of documentation and staff interview, the laboratory director failed to ensure a written procedure manual is available to the laboratory staff to review. Following included: 1. Surveyor requested and the laboratory director failed to provide a written procedure manual for testing performed in the laboratory. 2. At the time of the survey, the laboratory director failed to provide evidence of review and approval of test procedures performed in the laboratory. 3. In an interview on July 20, 2026 at 1:00pm in the laboratory office with the practice manager, the findings were confirmed.