Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 42D1088990	**(X3) Date Survey Completed** 07/23/2025
Name of Provider or Supplier Palmetto Pain Management, Llc	**Street Address, City, State** 2611 Forest Drive, Columbia, 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 onsite CLIA recertification survey was conducted on July 23, 2025, at the laboratory of Palmetto Pain Management 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 Condition and Standard level deficiencies cited as a result of the CLIA recertification survey on July 23, 2025. D2016 42 CFR 493.803 Successful Participation in Proficiency Testing.
D2016	SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c) (a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history. This CONDITION is not met as evidenced by: Based on records review, American Proficiency Institute (API) performance summary

	documentation, and staff interview, the labortory failed to successfully participate in a CMS approved proficiency testing (PT) program in 4 out of 4 events reviewed. Findings included: 1. Review of API PT results reveals to following: a. 2023 API Chemistry Miscellaneous 2nd event test pH score = 67% b. 2024 API Chemistry Miscellaneous 1st event test pH score = 33% c. 2024 API Chemistry Miscellaneous 2nd event test pH score = 67% d. 2025 API Chemistry Miscellaneous 1st event test pH score = 33% 2. Review of CLIA standards indicates 2 consecutive PT failures or 2 out of 3 PT failures for a given analyte constitutes "Unsuccessful" participation in PT program. 3. In an interview with General Supervisor (GS1) on July 23, 2025 at 1:45 pm in the laboratory breakroom, the findings were confirmed.
D6004	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(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, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (a) The laboratory director, if qualified, may perform the duties of the technical consultant, clinical consultant, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications of 493.1409, 493.1415, and 493.1421, 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 records review, API PT performance summaries, and staff interview, the laboratory director failed to ensure the successful participation in an approved PT program in 4 out of 4 events reviewed. Findings included: 1. Review of API PT results reveals to following: a. 2023 API Chemistry Miscellaneous 2nd event test pH score = 67% b. 2024 API Chemistry Miscellaneous 1st event test pH score = 33% c. 2024 API Chemistry Miscellaneous 2nd event test pH score = 67% d. 2025 API Chemistry Miscellaneous 1st event test pH score = 33% 2. Review of CLIA standards indicates 2 consecutive PT failures or 2 out of 3 PT failures for a given analyte constitutes "Unsuccessful" participation in PT program. 3. In an interview with General Supervisor (GS1) on July 23, 2025 at 1:45 pm in the laboratory breakroom, the findings were confirmed.