

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 42D1088990	(X3) Date Survey Completed 02/16/2024
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	A Recertification Survey was conducted at Palmetto Pain Management, Columbia, SC on 02/16/2024. The laboratory was found to be out of compliance with CLIA regulations 42CFR Part 493. Standard level deficiencies were cited.
D5431	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(2)</p> <p>For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document function checks as defined by the manufacturer and with at least the frequency specified by the manufacturer. Function checks must be within the manufacturer's established limits before patient testing is conducted.</p> <p>This STANDARD is not met as evidenced by: Based on the review of the laboratory's Agilent 6460 procedure manual, Maintenance Checklist for Agilent 6460, and staff interview, the laboratory failed to follow the laboratory's policy for documentation of instrument maintenance in 3 of 24 months. I Findings included: 1. Review of the Agilent 6460 procedure manual reveals the instrument manufacturer's maintenance requirement, which includes weekly maintenance. 2. Review of the Maintenance Checklist for Agilent 6460 for 2022 and 2023 revealed 3 of 24 months with no documentation of weekly maintenance. 3. In an interview on 02/16/2024 at 11:20 am in the laboratory conference room, the staff acknowledged no documentation of weekly maintenance for 01/2023, 02/2023, and 03 /2023. II Based on the review of the laboratory's Olympus AU400 e analyzer procedure manual, AU400e Analyzer Maintenance Log, and staff interview, the laboratory failed to follow the laboratory's policy for documentation of instrument maintenance 12 of 12 months in 2022. Findings included: 1. Review of the Olympus AU400e analyzer procedure manual reveals the instrument manufacturer's maintenance requirement, which includes quarterly maintenance. 2. Review of the Olympus AU400e Analyzer Maintenance log for 2022 revealed 12 of 12 months with no documentation of quarterly maintenance. 3. In an interview on 02/16/2024 at 11:25</p>

am in the laboratory conference room, the staff acknowledged no documentation of quarterly maintenance 12 of 12 months in 2022.