

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 11D0714805	(X3) Date Survey Completed 04/15/2025
Name of Provider or Supplier Nephrology Associates Pc	Street Address, City, State 701 Greene Street, Suite 200, Augusta, GA	
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 Clinical Laboratory Improvement Amendments (CLIA) recertification survey was completed on April 15, 2025. The laboratory was not in compliance with applicable CLIA requirements found at 42 CFR 493.1 through 42 CFR 493.1780. The following deficiencies were cited:
D5217	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on the review of American Proficiency Institute (API) proficiency testing (PT) documents and staff interview in the specialty of Chemistry, the laboratory failed to verify the accuracy of a non-regulated analyte by successfully passing two(2) (PT) events in 2023 and 2024. Findings: 1.) Review of 2023 and 2024 (API) (PT) documents revealed in the specialty of Chemistry, the laboratory received a score of 0% for Urine Microalbumin in events #1 and #2 of 2023. The laboratory also received a score of 60% for UIBC in event #2 of 2023 and 0% in UIBC event #3 of 2023. resulting in "Unsuccessful" notation by the PT agency. 2.) An interview with the lab manager (TP #4 CMS 209) on 04/15/2025 at approximately 2:00 PM confirmed the above findings and indicated that corrective action was done on the above events in 2023 and 2024.</p>
D6005	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(c)</p> <p>(c) The laboratory director must: (c)(1) Be onsite at least once every 6 months, with at least 4 months between the minimum two on-site visits. Laboratory directors may elect to be on-site more frequently and must continue to be accessible to the</p>

laboratory to provide telephone or electronic consultation as needed; and (c)(2) Provide documentation of these visits, including evidence of performing activities that are part of the laboratory director responsibilities.

This STANDARD is not met as evidenced by:

Based on maintenance records review and interview with the laboratory staff, the laboratory director failed to ensure that ALL pre analytic, analytic and post analytic Quality Assurance (QA) guidelines were followed to identify and fix problems in the laboratory in 2023 - 2024 as required by Clinical Laboratory Improvement Amendments (CLIA). Findings: 1. QA documents review revealed the lab director, who is also the (TC), did not identify QC trends on Levey Jennings charts correctly to rectify problems on the Beckman Coulter AU480 Chemistry analyzer in 2023 - 2024. 2. An interview with the laboratory manager (TP#4 CMS 209) in the review room, on 04/15/2025, at approximately 2:15 PM, confirmed the lab director , who is also the technical consultant (TC), failed to ensure proper oversight of the laboratory in 2023 - 2024.