

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 11D0262339	(X3) Date Survey Completed 07/23/2024
Name of Provider or Supplier Nephrology And Hypertension Specialists Pc	Street Address, City, State 1506 Broadrick Drive, Dalton, 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 recertification survey was performed on , July 23, 2024. The facility was found to be NOT in compliance with all applicable CLIA requirements for specialties /subspecialties for 42 CFR.
D5401	<p>PROCEDURE MANUAL CFR(s): 493.1251(a)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on Standard Operation Procedure manual (SOP) review and testing personnel (TP) interview, the laboratory failed to ensure an approved procedure was available for the Sulfosalicylic Acid (SSA) used for Total Protein verification. Findings include: 1. SOP review revealed the lack of a procedure to perform SSA. 2. An interview with TP# 2 (CMS 209) in the laboratory on 7/23/24 at 3:25 PM, confirmed the lack of the procedure for SSA.</p>
D5449	<p>CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(g)</p> <p>Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed.</p>

This STANDARD is not met as evidenced by:

Based on quality control (QC) document review and TP interview, the laboratory failed to perform and document QC on SSA. Findings include: 1. A review of the laboratory QC documents revealed that there was no QC data available to review on SSA at the time of survey. 2. An interview with TP# 2 (CMS 209) on 7/23/24 at 3:25 PM in the laboratory confirmed controls were not performed on SSA.