

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 11D0262339	(X3) Date Survey Completed 09/03/2020
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	On September 30, 2020, an off site followup review was completed. The report revealed that corrective action was found to be acceptable and corrected. The facility is now in compliance with with all regulations surveyed. An initial Clinical Laboratory Improvement Amendments (CLIA) survey was completed on September 03, 2020. The laboratory was not in compliance with all applicable CLIA requirements found at 42 CFR 493.1 through 42 CFR 493.1780. The following deficiencies were cited:
D5435	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(2)</p> <p>For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must: (i) Define a function check protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (ii) Perform and document the function checks, including background or baseline checks, specified in paragraph (b)(2)(i) of this section. Function checks must be within the laboratory's established limits before patient testing is conducted.</p> <p>This STANDARD is not met as evidenced by: Based on observation during the tour and laboratory director's interview, the laboratory failed to perform and document equipment maintenance as required. Findings include: 1. Observation during the laboratory tour on 09/03/2020 at approximately 09:45 a.m. revealed the Nikon Labopoint Microscope was last serviced on October 2018. 2. An interview with the laboratory director and the laboratory manager on 09/03/2020 at approximately 12:00 p.m. in the manager's review room confirmed the microscope was last serviced in October 2018.</p>