

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  11D0261560	<b>(X3) Date Survey Completed</b>  07/17/2025
<b>Name of Provider or Supplier</b>  Northeast Georgia Physicians Group Cleveland	<b>Street Address, City, State</b>  2578 Helen Highway, Cleveland, GA	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D0000</b>	A Clinical Laboratory Improvement Amendments (CLIA) recertification survey was completed on July 17, 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:
<b>D2007</b>	<p><b>TESTING OF PROFICIENCY TESTING SAMPLES</b> CFR(s): 493.801(b)(1)</p> <p>(b)(1) The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods.</p> <p>This STANDARD is not met as evidenced by: Based on review of the American Proficiency Institute (API) proficiency testing (PT) attestation sheets, competency evaluations, CMS 209 personnel report, and a staff interview the laboratory failed to rotate PT samples with all testing personnel (TP). Findings: 1. Review of the 2023, 2024, and 2025 competency evaluations and the CMS 209 personnel report revealed 5 testing personnel performing complete blood counts (CBC) on the Sysmex 350N analyzer. 2. Review of the API attestation forms of 2023 event 3; 2024 events 1, 2, &amp; 3; and 2025 event 1 revealed only 3 TP (TP #1, TP #2, TP #3) were running the PT samples for evaluation. 3. Interview with TP #1 (CMS 209) on 7/17/25 in the review office at 12:35 PM confirmed the aforementioned findings.</p>
<b>D5785</b>	<p><b>CORRECTIVE ACTIONS</b> CFR(s): 493.1282(b)(3)</p> <p>(b)(3) The criteria for proper storage of reagents and specimens, as specified under 493.1252(b), are not met.</p>

This STANDARD is not met as evidenced by:

Based on review of humidity records and staff interview, the lab failed to document corrective actions when relative humidity (RH%) exceeded acceptable limits of 10% to 80 %. Findings include: 1. Review of RH% records (June 2023 through Dec. 2024) revealed RH % were out of range 354 days of 579 days without corrective actions documented. 2. Interview with testing personnel #1 (CMS 209 form) on 7/17/25 at 12:45 PM in the review office, confirmed the corrective actions were not documented for the out of range RH%.