

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 11D2123762	(X3) Date Survey Completed 09/18/2025
Name of Provider or Supplier Northeast Georgia Physicians Group	Street Address, City, State 1429 Thompson Bridge Road, Gainesville, 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 September 18, 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:
D5413	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p> <p>(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (b)(1) Water quality. (b)(2) Temperature. (b)(3) Humidity. (b)(4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.</p> <p>This STANDARD is not met as evidenced by: A review of 2023 - 2025 Temperature Records, confirmed that the Laboratory failed to monitor the room temperature and room humidity to assure reliable test system operations as ascribed by the manufacturer. THE FINDINGS INCLUDE: 1. A review of 2023 - 2025 Temperature Records confirmed that documentation of the laboratory room temperature and room humidity was not monitored. 2. A review of Operating Manual for the Beckman Coulter AC*T Diff 2 Hematology analyzer confirmed that the optimal operating environment temperature of 20C - 25C and environment humidity of 20% - 85%. 3. An exit interview, with the Laboratory Director and the Technical Consultant, on September 18, 2025, at 12:30pm confirmed that the Laboratory failed to monitor the room temperature and room humidity to assure reliable test system operations as documented by the manufacturer.</p>

D6028

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(10)

(e)(10) Employ a sufficient number of laboratory personnel with the appropriate education and either experience or training to provide appropriate consultation, properly supervise and accurately perform tests and report test results in accordance with the personnel responsibilities described in this subpart;

This STANDARD is not met as evidenced by:

A review of 2023 - 2025 Personnel Records confirmed that the Laboratory Director (LD) failed to assure that testing personnel had the appropriate education to perform the duties of Testing Personnel (TP). THE FINDINGS INCLUDE: 1. A review of 2023 - 2025 Personnel Records revealed that proof of education was not available for TP5, TP7, TP9, TP10, and TP15(see Form 209 Laboratory Personnel Report (CLIA) form). 2. An exit interview, with the Laboratory Director and the Technical Consultant, on September 18, 2025, at 12:30pm, confirmed that the LD failed to assure that testing personnel had the appropriate education to accurately perform the duties of TP.