

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 11D0704164	(X3) Date Survey Completed 12/19/2018
Name of Provider or Supplier Northeast Georgia Physicians Group	Street Address, City, State 990 Loganville Highway, Bethlehem, 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 December 19, 2018. The laboratory was not in compliance with applicable CLIA requirements found at 42 CFR 493.1 through 42 CFR 493.1780. The following deficiency was cited:
D5437	<p>CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(a)</p> <p>Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (2) Using the criteria verified or established by the laboratory as specified in 493.1253(b) (3)-- (2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification.</p> <p>This STANDARD is not met as evidenced by: Based on review of Hematology calibration documents and an interview the laboratory coordinator Testing Personnel (TP#1 CMS 209), the laboratory failed to perform calibrations on the Cell-Dyn Emerald CBC Hematology analyzer at least once every 6 months in 2018. Findings include: 1. A review of hematology calibration records revealed calibrations were not performed in August 2018 as data dictated. 2. Calibrations were performed 2/15/2018 and 10/10/2018 (a 8 month gap), instead of August 2018 (6 months gap) as recommended by the manufacturer. 3. An interview with the laboratory coordinator TP #1 (CMS 209) at approximately 12:10 pm on 12/19 /18 in the review room confirmed Hematology calibrations was not performed within 6 months in 2018.</p>