

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 11D0869932	(X3) Date Survey Completed 09/22/2020
Name of Provider or Supplier Lagrange Internal Medicine	Street Address, City, State 1602 Vernon Road Suite 400, Lagrange, 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 22, 2020. 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:
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 staff interview, the laboratory failed to calibrate the CellDyn Ruby analyzer at least once every 6 months. Findings include: 1. Review of CellDyn Ruby calibration documents revealed calibrations were performed 10/4/18, 03/08/19, 01/28/20, and 06/17/20. There was a 10 month span between the calibrations done March 2019 and January 2020. 2. Interview with the technical consultant on 09/22/20 at approximately 1:00 PM in the conference room confirmed the span between calibrations being greater than 6 months.</p>