

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 34D1080075	(X3) Date Survey Completed 02/15/2023
Name of Provider or Supplier Novant Health Gateway Family Medicine	Street Address, City, State 390 W Salem Avenue, Winston-Salem, NC	
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
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 manufacturer's instructions, review of 2020, 2021, and 2022 calibration records, and interview with the TC (technical consultant) 2/15/23, the laboratory failed to perform and document calibration at least once every 6 months for the Medonic M-Series hematology analyzer. The Medonic M-Series Procedure Manual states "... CALIBRATION: Calibration must be performed upon setup of the instrument and then at a minimum of every 6 months. ..." Review of 2020, 2021, and 2022 calibration records revealed the Medonic M-Series hematology analyzer was calibrated 8/5/20, but not again until 6/29/21, a period of approximately 11 months. There was no documentation available to indicate why the instrument calibration was late. During interview at approximately 10:15 a.m., the TC stated that she was unsure why the calibration was late.</p>