Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 34D2141631	(X3) Date Survey Completed 11/27/2019
Name of Provider or Supplier Novant Health Pediatrics Symphony Park	**Street Address, City, State** 6010 Carnegie Boulevard, Charlotte, 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	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(a) 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. This STANDARD is not met as evidenced by: Based on review of manufacturer's standard operating procedure, review of the laboratory's procedure, and review of 2018 and 2019 calibration and laboratory records 11/27/19, the laboratory failed to calibrate the Medonic-M Hematology analyzer as required by the manufacturer's instructions and laboratory procedure. Findings: The Medonic M Series hematology analyzer standard operating procedure, under Calibration, states, "Calibration must be performed more frequently than every 6 months if: -Major maintenance is performed that could affect calibration -Troubleshooting indicates a need for recalibration -The instrument is moved to another location...." Review of the laboratory's procedure, "Medonic M-Series Hematology Analyzer", revealed the following: "Calibration of the analyzer using Boule Calibrator I is required as follows: 1. Upon initial installation 2. Every six(6) months 3. Major maintenance is performed that could affect calibration 4. Troubleshooting indicating a need for recalibration 5. The instrument is moved to another location...." Review of the 2018 and 2019 calibration records revealed the Medonic M analyzer was calibrated on 11/1/18. Review of laboratory records

	revealed the analyzer was relocated to a new facility on 1/4/19. The analyzer was not calibrated again until 5/17/19, when the 6-month calibration was due.