Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 30D0002717	**(X3) Date Survey Completed** 12/08/2020
Name of Provider or Supplier Concord Hospital - Franklin	**Street Address, City, State** 15 Aiken Ave, Franklin, NH	
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**
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to perform calibration verifications procedures every six months in 2020 for routine chemistry and toxicology analytes. Findings include: 1) Review on 12/7/2020 of the laboratory calibration verification records for the Siemens Vista 500 (Vista) analyzer revealed the most recent calibration verification was performed in January 2020. Further review of the calibration verification records revealed calibration verification is

	required for the following (less than 3 calibration standards documented on the analyte list): acetaminophen, albumin, alkaline phosphatase, alanine aminotransferase, ammonia, amylase, aspartate aminotransferase, blood urea nitrogen, calcium, cholesterol, creatine kinase, carbon dioxide, creatinine, director bilirubin, ethanol, glucose, high-density lipoprotein, iron, lactate, lipase, magnesium, phosphate, prealbumin, salycilates, total bilirubin, total iron binding capacity, total protein, triglycerides, and uric acid. 2) Interview on 12/7/2020 at approximately 9:30 a.m. with the technical supervisor (TS1) confirmed calibration verification procedures for the Vista analyzer had not been performed since January 2020.