

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 30D1023469	(X3) Date Survey Completed 08/31/2018
Name of Provider or Supplier Quest Diagnostics	Street Address, City, State 14 Tsienneto Rd, Ste 201, Derry, 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	<p>CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to verify calibration of chemistry analytes' reportable ranges in 2016, 2017 and 2018. Findings include: 1) Review on 8/31/18 of calibration verification records from December 2016 through August 2018 for blood urea nitrogen (BUN) and creatinine revealed the material used for calibration verification procedures did not have expected values. Calibration verification performed on 5/25/2018 for BUN and creatinine failed to meet acceptable</p>

criteria and was repeated on 6/19/2018 which failed to include peer data for use as expected values to verify the laboratory's reportable ranges. Further review revealed peer data was not obtained and used to verify the laboratory's reportable ranges during calibration verification performed on 12/22/2016 for BUN and Creatinine and on 12/27/2017 for creatinine. 2) Interview on 8/31/2018 at 12:45 p.m. with the Technical Consultant and Laboratory Director confirmed the above finding. 3) The laboratory performs approximately 100 BUN and creatinine tests annually.