

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 33D0129943	(X3) Date Survey Completed 04/02/2019
Name of Provider or Supplier Park Avenue Endocrinology & Nutrition Pllc	Street Address, City, State 103 East 75th Street, New York, NY	
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 lack of calibration verification records and an interview with the laboratory technical consultant, and testing person, the laboratory failed to perform calibration verification at least once every six months for the chemistry tests performed on the Pentra C400 analyzer. FINDINGS: 1. The laboratory performs a one-point calibration for all analytes, tested on the ABX Pentra C400, therefore, the laboratory is required to perform calibration verification every six months. 2. On April 2, 2019, at</p>

approximately 12:45 PM, it was discovered and confirmed by the technical consultant that the laboratory has never performed perform calibration verification at least every six months since they obtained their analyzer in May 2017. 3. The ABX Pentra C 400 analyzer was out of calibration verification from November 2017 through April 2, 2019. 4. Approximately 13401 patient specimens were tested and reported for chemistry analytes when the Pentra C400 analyzer was out of calibration verification.

D6020

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(5)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that the quality control program is established and maintained to assure the quality of laboratory services provided.

This STANDARD is not met as evidenced by:
Based on the surveyor's review of calibration records and confirmed, during this onsite survey with the technical consultant and the testing person, the laboratory director failed to ensure that the QC program for chemistry testing was maintained to assure the quality of laboratory services. Refer to: D5439