

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 33D0146932	(X3) Date Survey Completed 08/16/2018
Name of Provider or Supplier Crown Medical Pc	Street Address, City, State 358 Kingston Avenue, Brooklyn, 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 the surveyor's review of the laboratory's calibration verification records and an interview with the office manager and testing person, the laboratory failed to perform calibration verification at least once every six months for chemistry testing on the Horiba Pentra 400 chemistry analyzer from 9/1/2017 through 6/1/2018. FINDINGS: The office manager and testing person confirmed on August 16, 2018 at approximately 10:45 AM, the laboratory failed to perform calibration verification at</p>

least once every six months for chemistry testing on the Horiba Pentra 400 analyzer a. the laboratory performed a calibration verification on 3/1/17, therefore the Pentra 400 was out of calibration from 9/1/17 through 6/1/18. b. approximately 267 patients samples were tested during this time period.