

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 22D0077095	(X3) Date Survey Completed 06/09/2021
Name of Provider or Supplier Faulkner Medical Laboratories, Inc	Street Address, City, State 410 Ferry St, Malden, MA	
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
D0000	A CLIA recertification survey was conducted for Faulkner Medical Laboratories, Inc pursuant to the Clinical Laboratory Improvement Amendments (CLIA) of 1988 and CLIA regulations at 42 CFR 493.
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 interview on 6/9/2021, the laboratory failed to perform and document calibration verifications as appropriate as evidenced by the following:</p>

The surveyor reviewed quality control records on 6/9/2021 for calendar years 2019, 2020, and 2021. The review revealed that calibration verifications of at least 3 points were not performed once every six months for twenty one (21) out of twenty one (21) chemistry analytes requiring calibration verifications tested on the ELITech Envoy 500 Chemistry analyzer. The last documented calibration verifications were performed on 6/13/2020. The Testing Person and laboratory owner confirmed through interview on 6/9/2021 at 11:00 AM that calibration verifications of at least 3 points had not been performed at least once every six months for all Routine Chemistry analytes. The laboratory performs approximately 63,055 Routine Chemistry tests annually.