Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	17D0451007	07/15/2020
Name of Provider or Supplier	**Street Address, City, State**	
El Dorado Clinic	700 W Central, Ste 205, El Dorado, KS	

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: A review of calibration verification records for the Abbott Cell-Dyn Emerald analyzer, and interview with staff revealed that the laboratory failed to perform calibration verification once every six months. One of two calibration verifications were performed in 2019 on the Cell-Dyn Emerald analyzer. Finding were as follows 1. Review of the Abbott Cell-Dyn Emerald verification documentation revealed the laboratory failed to perform calibration verification at least once every six months.

	The laboratory performed a calibration verification on May 2, 2019 but failed to perform the calibration verification that was due in November 2019. A calibration verification for March 11,2020 was performed. 2. Interview with the technical consultant #2 confirmed that only one of the two required calibration verification was performed in 2019 for the Abbott Cell-Dyn Emerald analyzer.