Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	44D2047964	01/06/2020
Name of Provider or Supplier	**Street Address, City, State**	
Quality Of Life Healthcare, Inc	302 Wesley St Suite 3, Johnson City, TN	

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: ========== Based on review of manufacturer's requirements for calibration verification for the Piccolo, lack of calibration verification documentation for 2019 and upon interview with the Laboratory Technical Consultant, it was determined the laboratory failed to perform calibration verifications for the Piccolo for the 12 non-waived analytes being tested. The findings include: 1. A review of the manufacturer's requirements for the Piccolo states that

	calibration verification is to be performed every 6 months. 2. There were no calibration verifications documented for 2019. 3. An interview at approximately 2:30 p.m. January 6, 2020 with the Laboratory Technical Consultant confirmed the laboratory had not performed calibration verifications on the Piccolo for 2019. ==========