Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	44D2040017	09/10/2021
Name of Provider or Supplier	**Street Address, City, State**	
University Health System	1130 Middle Creek Rd, Suite 160, Sevierville, 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 a review of the Laboratory's Procedure, Calibration Verification records and interview with the Lead Testing Person determined the laboratory failed to ensure calibration verification was performed every six months for 2019 and 2020. The findings include: 1. A review of the Laboratory's Procedure for Calibration Verification stated that Calibration Verification is to be done every six months. 2. A review of Calibration Verification

	records for the hematology analyzer showed the following: -calibration was performed on 06.11.2019 and 09.16.2020, equaling a 15 month period between calibrations -calibration was performed on 09.16.2020 and 09.03.2021, equaling a 12 month period between calibrations 3. An interview with the Lead Testing Person at 2: 35 p.m. on September 9, 2021 confirmed the calibration verifications for the Hematology Analyzer were not performed every six months for the two year period. ==========