Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2110515	03/13/2018
Name of Provider or Supplier	**Street Address, City, State**	
Chi St Luke's Health Memorial Emergency Center	501 N Brentwood Drive, Lufkin, TX	

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 calibration verification documentation from 01-17-2017 through 11-18-2017 for the Abbott I-Stat chemistry analyzer, confirmed by staff interview, the laboratory failed to perform calibration verification on i-STAT cartridge types CG4+, BNP, B-hCG, and cTnI every six months. Findings: 1. Calibration verification documentation for the year 2017 was reviewed. Documentation showed calibration verification for cartridge type CG4+, used to test for hydrogen ion concentration (pH),

	carbon dioxide pressure (pCO2), oxygen pressure (pO2) and lactic acid (Lact), cartridge type BNP, used to test for brain natriuretic peptide (BNP), cartridge type B-hCG, used to test for beta-human chorionic gonadotropin (BHCG) and cartridge type cTnI, used to test for troponin-I, performed on 01-17-2017 and 11-18-2017. 2. In an interview at the site, the laboratory technical consultant (CMS form 209) stated no other calibration verification had been performed on the above cartridge types between 01-17-2017 and 11-18-2017. .