Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	44D2093391	05/14/2025
Name of Provider or Supplier	**Street Address, City, State**	
State Of Franklin Healthcare, Wic	301 Med Tech Pkwy, Suite 110, 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) (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 laboratory observation, a review of calibration verification records for the Chemistry EPOC Blood Analysis System, and an interview with the laboratory technical consultant, the laboratory failed to ensure calibration verification at six-month intervals during 2024. The findings include: 1. Observation of the laboratory on 05.14.2025 at 9 a.m. revealed an EPOC Blood Analysis System (serial # 53093) used for patient testing for chemistry analytes. 2. A review of calibration verification records for the EPOC Blood Analysis System for Blood Urea Nitrogen (BUN), Chloride, Carbon Dioxide (CO2), Creatinine, Glucose, Ionized Calcium, Sodium, and Potassium revealed no documentation of calibration verification at 6 months

	(documented on 03.24.2024 only) in 2024. 3. An interview with the laboratory technical consultant on 05.14.2025 at 12:05 p.m. and a follow-up electronic communication on 05.20.2025 at 5:04 p.m. confirmed the above survey findings.