Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	26D1078861	08/22/2023
Name of Provider or Supplier	**Street Address, City, State**	
Select Specialty Hospital - Springfield, Inc	1630 E Primrose, Springfield, MO	

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 blood gas procedures, Gem Premier 3500 blood gas analyzer calibration verification and interview with testing personnel (TP) #1, the laboratory failed to ensure acceptable limits were met for PCO2 calibration verification for two of four calibrations. Findings: 1. Review of Gem Premier 3500 analyzer procedure states "Calibration Verification, Complete PVP's in June & December". 2. Review of Gem Premier 3500 blood gas analyzer calibration verification showed in December

	2022 for analyte PCO2 one of four samples did not meet acceptable limits for accuracy and the linearity summary stated "1 of 4 fail". 3. Review of Gem Premier 3500 blood gas analyzer calibration verification showed in June 2023 for analyte PCO2 two of four samples did not meet acceptable limits for accuracy and linearity summary stated "2 of 4 fail". 4. Interview with TP #1 on August 22, 2023 at 10:00 AM confirmed the laboratory failed to ensure acceptable limits were met for PCO2 calibration verification for two calibrations.