Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	03D0527938	04/26/2023
Name of Provider or Supplier	**Street Address, City, State**	
Sobel Family Medicine	4550 E Bell Rd #114, Phoenix, AZ	

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 lack of calibration verification documentation for testing performed on the i-Stat analyzer and the Beckman Coulter DXH 520 analyzer and interview with the facility personnel, the laboratory failed to perform and document calibration verification procedures as required. Findings include: 1. The laboratory performs Chem8+ testing on the i-Stat analyzer under the specialty of Chemistry, and performs Complete Blood Count (CBC) testing on the Beckman Coulter DXH 520 analyzer

	under the specialty of Hematology. The laboratory's approximate annual test volume for each specialty is 25,000. 2. No documentation was presented for review to indicate the laboratory performed a calibration verification on the i-Stat analyzer at least once every six months during 2021 and 2022, 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. 3. Calibration verification documentation reviewed during the survey conducted on 4/26/2023 for the i-Stat analyzer indicated the lab performed a calibration verification on 7/01/2020, with the next calibration verification performed on 10/05/2022. 4. No documentation was presented for review to indicate the laboratory performed a calibration verification on the DXH 520 analyzer at least once every six months during 2022, 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. 5. Calibration verification documentation reviewed during the survey conducted on 4/26/2023 for the DXH 520 analyzer indicated the lab performed a calibration verification in November 2022, with the previous calibration verification performed in July 2021. 6. The facility personnel interviewed on 4/26/2023 at 2:55pm acknowledged that calibration verification was not performed every 6 months on the I-stat analyzer and the DXH 520 analyzer as required.