Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 53D2135798	(X3) Date Survey Completed 03/20/2023
Name of Provider or Supplier Sugarland Walk In Clinic	**Street Address, City, State** 1005 Sugarland Drive, Sheridan, WY	

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 documentation, review of the Abbott iSTAT manufacturer's instructions, and staff interview, the laboratory failed to verify the reportable range at least every 6 months using testing materials with values at the zero or minimal level, the mid-level, and the upper-level of the reportable range for the CHEM8+ test cartridge (sodium, potassium, chloride, ionized calcium, glucose, blood urea nitrogen, creatinine, total carbon dioxide, hematocrit, and hemoglobin) for 2 of 2 years of

	testing (2021, 2022) reviewed. The laboratory performed approximately 3,204 patient tests annually using the Abbott iSTAT instrument. The findings were: 1. Review of the laboratory's records showed no documentation the reportable range of the analytes tested on the Abbott i-STAT instrument had been verified. 2. Review of the Abbott iSTAT manufacturer's instructions, last revised 2/26/20, showed "Calibration verification procedure is intended to verify the accuracy of results over the entire measurement range of a test as may be required by regulatory or accreditation bodies." 3. Interview with the technical consultant on 3/20/23 at 3 PM confirmed the calibration verification studies had not been completed.