

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 13D0673165	(X3) Date Survey Completed 08/16/2023
Name of Provider or Supplier Blackfoot Medical Center	Street Address, City, State 1441 Parkway Dr, Blackfoot, ID	
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	<p>CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on record review of calibration documentation for the Siemens Immulite and an interview with the laboratory manager on 8/16/2023, the laboratory failed to perform calibration verification at least every 6 months in 2022 and 2023. The findings include: 1. A record review of calibration and calibration verification documentation for the Siemens Immulite 2000XPi identified that the laboratory failed to perform calibration verification which included a minimal, mid-point and maximum value at</p>

least every 6 months for follicle stimulating hormone (FSH), lutenizing hormone (LH), progesterone, insulin, parathyroid hormone (PTH), sex hormone binding globulin (SHBG) and testosterone in 2022 and 2023. 2. An interview with the laboratory manager on 8/16/2023 at 3:19 pm confirmed that the laboratory failed to perform calibration verification for the above analytes in 2022 and 2023. 3. The laboratory reports performing 2,217 patient tests annually on the Siemens Immulite 2000XPi analyzer.