Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	27D0041965	10/27/2021
Name of Provider or Supplier	**Street Address, City, State**	
Big Horn Hospital Association	17 North Miles Avenue, Hardin, MT	

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
D2096	ROUTINE CHEMISTRY CFR(s): 493.841(f) Failure to achieve satisfactory performance for the same analyte or test in two consecutive testing events or two out of three consecutive testing events is unsuccessful performance. This STANDARD is not met as evidenced by: Based on record review of American Proficiency Institute (API) proficiency testing scores for chemistry and interview with the Technical Supervisor (TS) #1, the laboratory failed to achieve satisfactory performance for 25-OH Vitamin D for two out of three events in 2021. Findings: 1. Review of American Proficiency Institute (API) proficiency testing scores for 2021 Chemistry Core revealed unsuccessful proficiency testing for 25-OH Vitamin D with a 50% score for 2021 Event 1 and 50% score for 2021 Event 2. 2. Interview with the TS #1 on October 26, 2021 at 3:22 PM confirmed the laboratory failed to achieve satisfactory performance for 25-OH Vitamin D for two out of three events in 2021.
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 calibration records for the Abbott i-STAT Analyzer using EG6+ cartridge (Sodium, Potassium, Hematocrit, pH, PCO2, PO2) and G3+ cartridge (pH, PO2, PCO2) and interview with the Technical Supervisor (TS) #1, the laboratory failed to perform at least a three-point (a minimal, mid-point, and maximum) calibration verification every six months or after CLEW software updates for years 2020 and 2021. Findings: 1. Review of 2020 and 2021 calibration records for Abbott i-STAT analyzer for analytes Sodium, Potassium, Hematocrit, pH, PCO2, PO2 revealed the laboratory failed to perform a calibration verification including, at least, a minimal, midpoint, and maximum value for each analyte, performed every six months or after CLEW software updates for years 2020 and 2021. 2. Interview with the TS #1 on October 27, 2021 at 9:24 AM, confirmed the laboratory failed to perform at least a three-point calibration verification for analytes Sodium, Potassium, Hematocrit, pH, PCO2, PO2, on the i-STAT analyzer every six months or after CLEW software updates for years 2020 and 2021.