Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	35D0926532	03/16/2021
Name of Provider or Supplier	**Street Address, City, State**	
Coal Country Community Health Center	Laboratory, Beulah, ND	

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 record review, staff interview, and policy review, the laboratory failed to verify calibration for 4 of 4 analytes (amylase, conjugated bilirubin, unconjugated bilirubin, and lipase) not calibrated at least once every six months in 2020. Findings include: 1. Reviewed at 12:00 p.m. on 03/16/21, the 2019-2021 Ortho Vitros calibration records indicated the laboratory did not calibrate the following analytes every six months during these timeframes: - Amylase calibrated on 08/02/19 and next

	on 07/13/20 (approximately 11 months); - Conjugated bilirubin calibrated on 08/05/19 and next on 05/13/20 (approximately 9 months); - Unconjugated bilirubin calibrated on 08/05/19 and next on 05/13/20 (approximately 9 months); and - Lipase calibrated on 08/02/19 and next on 07/13/20 (approximately 11 months). 2. Upon request at 1:25 p.m. on 03/16/21, the laboratory failed to provide evidence of calibration verification for amylase, conjugated bilirubin, unconjugated bilirubin, and lipase in 2020. 3. During interview at 1:25 p.m. on 03/16/21, a technical consultant (#1) confirmed the laboratory did not calibrate amylase, conjugated bilirubin, unconjugated bilirubin, and lipase at least every six months in 2020 and had not verified calibration for these analytes in 2020. 4. Reviewed at 4:15 p.m. on 03/16/21, the undated policy "Chemistry Vitros" stated, ". . . Calibration 1. Calibration - will be done: . . . c) government regulations specify - every six months . . ."