

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  35D0926532	<b>(X3) Date Survey Completed</b>  02/10/2025
<b>Name of Provider or Supplier</b>  Coal Country Community Health Center	<b>Street Address, City, State</b>  Laboratory, Beulah, ND	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D5439</b>	<p><b>CALIBRATION AND CALIBRATION VERIFICATION</b> CFR(s): 493.1255(b)</p> <p>(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, staff interview, and policy/procedure review, the laboratory failed to verify calibration at least every six months for 1 of 2 analytes (Vitamin B12) calibrated with less than three calibrators on the Vitros 5600 in 2024. The laboratory performed approximately 400 Vitamin B12 patient tests in 2024. Findings include: 1. Reviewed on 02/10/25, the 2024 Vitamin B12 calibration records indicated the use of two levels of calibrators for calibration of Vitamin B12. 2. Reviewed on 02/10/25, the 2024 calibration verification records failed to include Vitamin B12. 3. Upon request on 02/10/25, the laboratory failed to provide evidence of calibration verification at least twice annually for Vitamin B12 in 2024. 4. During interview at 12:10 p.m. on 02</p>

/10/25, the laboratory manager (#1) confirmed the laboratory had failed to verify calibration at least twice annually for Vitamin B12 in 2024. 5. Reviewed on 02/10/25, the policy/procedure "Ortho Vitros 5600," dated 09/2022, failed to include a requirement for at least twice annual calibration verification for analytes calibrated with less than levels of calibrators.