

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 35D0409330	(X3) Date Survey Completed 03/17/2021
Name of Provider or Supplier Trenton Community Clinic	Street Address, City, State 331 4th Ave E, Trenton, 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	<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 and staff interview, the laboratory failed to verify calibration for 8 of 8 analytes (albumin, alanine aminotransferase [ALT], urea nitrogen [BUN], calcium, cholesterol, creatinine, high density lipoprotein [HDL] cholesterol, and triglycerides) not calibrated at least once every six months in 2019-2020. Findings include: 1. Reviewed at 11:50 a.m. on 03/17/21, the 2019-2020 Ortho Vitros calibration records indicated the laboratory did not calibrate the following analytes</p>

every six months during these timeframes: - Albumin calibrated on 09/23/19 and next on 06/10/20 (approximately 8 months); - ALT calibrated on 05/04/19 and next on 12/28/19 (approximately 7 months); calibrated on 05/04/20 and next on 12/28/20 (approximately 7 months); - BUN calibrated on 01/17/19 and next on 11/19/19 (approximately 10 months); - Calcium calibrated on 01/17/19 and next on 08/22/19 (approximately 7 months); calibrated on 05/08/20 and next on 12/06/20 (approximately 7 months); - Cholesterol calibrated on 03/02/20 and next on 10/13/20 (approximately 7 months); - Creatinine calibrated on 01/17/19 and next on 09/24/19 (approximately 8 months); calibrated on 11/19/19 and next on 09/24/20 (approximately 10 months); - HDL cholesterol calibrated on 03/02/20 and next on 11/02/20 (approximately 8 months); and - Triglycerides calibrated on 03/02/20 and next on 10/13/20 (approximately 7 months). 2. Upon request at 1:50 p.m. on 03/17/21, the laboratory failed to provide evidence of calibration verification for albumin, ALT, BUN, calcium, cholesterol, creatinine, HDL cholesterol, and triglycerides in 2019-2020. 3. During interview at 1:50 p.m. on 03/17/21, the laboratory supervisor (#1) confirmed the laboratory did not calibrate albumin, ALT, BUN, calcium, cholesterol, creatinine, HDL cholesterol, and triglycerides at least every six months in 2019-2020 and had not verified calibration for these analytes in 2019-2020. 4. Upon request at 1:50 p.m. on 03/17/21, the laboratory failed to provide a policy regarding calibration and calibration verification requirements.