| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
|---|---|---|
| | 35D0669946 | 06/03/2026 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Ashley Medical Center | 612 Center Ave N, Ashley, 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 |
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| **D5439** | CALIBRATION AND CALIBRATION VERIFICATION<br>CFR(s): 493.1255(b)<br><br>(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.<br><br>This STANDARD is not met as evidenced by:<br>Based on record review and staff interview, the laboratory failed to verify calibration for 8 of 8 analytes (alkaline phosphatase [ALK], amylase, calcium, cholesterol, lactic acid, lipase, magnesium, and uric acid) not calibrated at least once every six months in 2024-2026. The laboratory performed 1,997 ALK, 95 amylase, 2,275 calcium, 470 cholesterol, 301 lactic acid, 190 lipase, 156 magnesium, and 43 uric acid patient tests the past year. Findings include: 1. Reviewed at 11:45 a.m. on 06/03/26, the 2024-2026 Ortho Vitros 5600 calibration records indicated the laboratory did not calibrate the following analytes every six months during these timeframes: - ALK calibrated on 03 /31/25 and next on 11/07/25 (approximately 7 months); - Amylase calibrated on 02/17 |

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| | /25 and next on 09/15/25 (approximately 7 months); - Calcium calibrated on 04/15/25 and next on 11/12/25 (approximately 7 months); - Cholesterol calibrated on 12/05/24 and next on 07/04/25 (approximately 7 months); - Lactic acid calibrated on 02/26/25 and next on 09/12/25 (approximately 7 months); - Lipase calibrated on 04/07/25 and next on 11/21/25 (approximately 7 months); - Magnesium calibrated on 01/06/25 and next on 08/01/25 (approximately 7 months); - Uric acid calibrated on 03/17/25 and next on 10/13/25 (approximately 7 months); and calibrated on 10/13/25 and next on 05 /13/26 (approximately 7 months). 2. Upon request at 1:08 p.m. on 06/03/26, the laboratory failed to provide evidence of calibration verification for ALK, amylase, calcium, cholesterol, lactic acid, lipase, magnesium, and uric acid in 2024-2026. 3. During interview at 1:45 p.m. on 06/03/26, a general supervisor (#1) confirmed the laboratory did not calibrate ALK, amylase, calcium, cholesterol, lactic acid, lipase, magnesium, and uric acid at least every six months in 2024-2026 and had not verified calibration for these analytes in 2024-2026. |
| **D6054** | TECHNICAL CONSULTANT RESPONSIBILITIES<br>CFR(s): 493.1413(b)(9)<br><br>(b)(9) Thereafter, evaluations must be performed at least annually<br><br>This STANDARD is not met as evidenced by:<br>Based on record review, staff interview, and policy review, the technical consultant failed to evaluate and document the competency of 2 of 3 testing personnel (#1 and #2) requiring annual competency evaluations in 2024 and 2025. Findings include: 1. Reviewed at approximately 10:20 a.m. on 06/03/26, the competency evaluation records for Testing Personnel #1 and #2 lacked evidence of a urine microscopic annual competency evaluation in 2024 and 2025. 2. During interview at 10:43 a.m. on 06/03/26, a general supervisor (#1) confirmed the laboratory had not completed a urine microscopic annual competency evaluation for Testing Personnel #1 and #2 in 2024 and 2025. 3. Reviewed the morning of 06/03/26, the undated policy, "Competency Plan," stated, "Documentation for . . . competency plan includes: List of test method grouping . . . Summary of annual competency evaluation for each employee . . ." |