

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 35D0408762	(X3) Date Survey Completed 03/23/2026
Name of Provider or Supplier Dakota Regional Medical Center Hospital Laboratory	Street Address, City, State 107 12th St S, Cooperstown, 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
D5215	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(2)</p> <p>The laboratory must verify the accuracy of any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect laboratory test performance (that is, when the proficiency testing program does not obtain the agreement required for scoring as specified in subpart I of this part, or the laboratory receives a zero score for nonparticipation, or late return or results).</p> <p>This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to verify the accuracy of proficiency testing results for 3 of 3 regulated analytes (Total Bilirubin, Creatine Kinase [CK], and Troponin) the College of American Pathologists (CAP) assigned as not graded. The laboratory performed 1,776 Total Bilirubin patient tests, 139 CK patient results, and 440 Troponin patient tests in the last year. Findings include: 1. Reviewed the morning of 03/23/26, the laboratory failed to evaluate the following not graded proficiency testing results: - Event C-C 2025 General Chemistry/Therapeutic Drugs - Total Bilirubin, sample CHM-13 - Event C-B 2025 General Chemistry/Therapeutic Drugs - CK, sample CHM-07 - Event C-A 2025 General Chemistry/Therapeutic Drugs - CK, sample CHM-03 - Event PCARM-C 2025 Point-of-Care Cardiac Markers - Troponin, sample PCAR-12 2. During interview at 1:46 p. m. on 03/23/26, a general supervisor (#1) confirmed the laboratory failed to evaluate the Event C-C 2025 Total Bilirubin not graded results, Event C-B 2025 CK not graded results, Event C-A 2025 CK not graded results, and Event PCARM-C 2025 Troponin not graded results. 3. Upon request, the laboratory failed to provide a policy related to not graded proficiency testing results.</p>
D6054	<p>TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9)</p>

(b)(9) Thereafter, evaluations must be performed at least annually

This STANDARD is not met as evidenced by:

Based on record review and staff interview, the technical consultant failed to evaluate and document the competency of 2 of 2 testing personnel (#1 and #2) requiring annual competency evaluations in 2024 and 2025. Findings include: 1. Reviewed at approximately 10:30 a.m. on 03/23/26, 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 11:09 a.m. on 03/23/26, 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. Upon request, the laboratory failed to provide a policy related to annual competency evaluations.