Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	35D0667372	03/02/2026
Name of Provider or Supplier	**Street Address, City, State**	
Linton Regional Medical Center	111 Elm Ave W, Linton, 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
D5211	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a) The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part. This STANDARD is not met as evidenced by: Based on record review, policy review, and staff interview, the laboratory failed to review and evaluate proficiency testing results for 2 of 3 American Association of Bioanalysts - Medical Laboratory Evaluation (AAB-MLE) events (Events 1 and 3) in 2025. Findings include: 1. Reviewed on the morning of 03/02/26, the following proficiency testing event records lacked evidence of results review and evaluation of analytes with less than 100% scores: - Event 1 2025 Lymphocyte % - 80% - Event 3 2025 Vaginal Wet Mount - 0% 2. Reviewed on 03/02/26, the undated "Proficiency Testing" policy, stated, ". . . If an unsatisfactory result is reported, follow up corrective action is required. The 'Proficiency Testing Unacceptable Result' form is filled out. . . ." 3. During an interview at 11:17 a.m. on 03/02/26, the laboratory director (#1) confirmed the laboratory had failed to document review of the Event 1 2025 and Event 3 2025 AAB-MLE results and evaluation of the results with less than 100% scores.
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(g) (d) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- (d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493. 1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the

	laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (d)(3) At least once each day patient specimens are assayed or examined perform the following for: This STANDARD is not met as evidenced by: Based on record review, quality control plan review, and staff interview, the laboratory failed to follow their Individualized Quality Control Plan (IQCP) for quality control (QC) performance for 1 of 3 IQCPs reviewed (Commercially Prepared "CLSI [Clinical & Laboratory Standards Institute] -Exempt" Media). The laboratory performed 530 patient urine cultures the past year. Findings include: 1. Reviewed at 2: 10 p.m. on 03/02/26, the QC records for commercially prepared CLSI-exempt media lacked the manufacturer's QC certification provided with each batch/lot/shipment of media upon receipt of shipment as stated in the laboratory's IQCP. 2. Reviewed at 2: 12 p.m. on 03/02/26, the laboratory's IQCP for commercially prepared CLSI-exempt media, last reviewed 12/30/25, stated, "Review of manufacturer's QC Certification provided with each batch/lot/shipment of media upon receipt of shipment." 3. During an interview at 2:31 p.m. on 03/02/26, the laboratory director (#1) confirmed the laboratory's IQCP requires review of manufacturer's QC certification and the laboratory failed to document the review and retain the manufacturer's QC certification.