Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	35D0655641	03/24/2026
Name of Provider or Supplier	**Street Address, City, State**	
Nelson County Health System	200 N Main St, Mcville, 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
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) (a)(1) Maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to perform required quarterly maintenance for 3 of 4 quarters (1st quarter 2025 [January 2025 through March 2025], 2nd quarter [April 2025 through June 2025], and 3rd quarter [July 2025 through September 2025]) reviewed. The laboratory performed 261 PT/INR (Prothrombin Time/International Normalized Ratio) patient tests the past year. Findings include: 1. Reviewed at 2:31 p.m. on 03/24/26, the Sysmex CA600 Operator's Maintenance Checklist showed the quarterly check "Clean DI (deionized) Water Rinse Bottle With Alcohol." 2. Reviewed the afternoon of 03/24/26, the 1st quarter 2025, 2nd quarter 2025, and 3rd quarter 2025 maintenance checklists for the Sysmex CA600 series lacked evidence of the quarterly "Clean DI Water Rinse Bottle With Alcohol" maintenance performance. 3. During an interview at 2:39 p.m. on 03/24/26, a laboratory director (#1) confirmed the laboratory had not completed the quarterly "Clean DI Water Rinse Bottle With Alcohol" maintenance for the 1st quarter 2025, 2nd quarter 2025, and 3rd quarter 2025.
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, plan review, and staff interview, the laboratory failed to follow their Individualized Quality Control Plan (IQCP) for quality control performance for 2 of 12 months reviewed (September 2025 and October 2025) for CoV-2/Flu/RSV (SARS-Coronavirus-2/ Influenza A and B/Respiratory Syncytial Virus) test cartridges on the Cepheid GeneXpert. The laboratory performed 114 patient CoV-2/Flu/RSV tests in the past year. Findings include: 1. Reviewed the afternoon of 03/24/26, the laboratory's Cepheid GeneXpert Xpress Quality Control Plan, dated 04/28/22, stated "External QC Samples: QC (Normal and Abnormal) will be tested every 30 days." 2. Reviewed at 1:45 p.m. on 03/24/26, the QC (quality control) records for CoV-2/Flu/RSV performed on the Cepheid GeneXpert indicated the laboratory failed to perform two levels of QC for the months of September 2025 and October 2025 as stated in the laboratory's IQCP. 3. During an interview the afternoon of 03/24/26, a laboratory director (#1) confirmed the laboratory's IQCP for CoV-2/Flu/RSV on the Cepheid GeneXpert required performance of two levels of QC every 30 days and the laboratory failed to perform two levels of QC in September 2025 and October 2025.