Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	35D0693180	03/03/2026
Name of Provider or Supplier	**Street Address, City, State**	
South Central Health	1007 4 Ave S, Wishek, 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 14 of 15 months (December 2024 through April 2025 and June 2025 through February 2026) reviewed. The laboratory performed 457 PT/INR (Prothrombin Time/International Normalized Ratio) and 36 PTT (Partial Thromboplastin Time) patient tests the past year. Findings include: 1. Reviewed at 10: 39 a.m. on 03/03/26, the Sysmex CA600 series maintenance log showed the quarterly check "Clean DI (deionized) Water Rinse Bottle With Alcohol." 2. Reviewed at approximately 10:40 a.m. on 03/03/26, the December 2024 through April 2025 and June 2025 through February 2026 maintenance logs for the Sysmex CA600 series lacked evidence of the quarterly "Clean DI Water Rinse Bottle With Alcohol" maintenance performance. 3. Upon request, the laboratory failed to provide a policy related to Sysmex CA600 series maintenance. 4. During an interview at approximately 1:00 p.m. on 03/03/26, a technical consultant (#1) confirmed the laboratory had not completed the quarterly "Clean DI Water Rinse Bottle With Alcohol" maintenance in December 2024 through April 2025 and June 2025 through February 2026.
D6087	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(3)(iii) (e)(3)(iii) Laboratory personnel are performing the test methods as required for accurate and reliable results;

	This STANDARD is not met as evidenced by: Based on record review, observation, and staff interview, the laboratory failed to use the correct patient normal mean for calculating International Normalized Ratios (INRs) for 13 of 13 months (January 17, 2025 - March 3, 2026) since the laboratory began using a new lot number of reagent for approximately 457 patient results. Failure to use the correct patient normal mean has the potential to affect the treatment of patients monitored with INRs. Findings include: 1. Reviewed at 10:39 a.m. on 03/03 /26, the laboratory's validation studies for the patient normal mean, dated 01/17/25, indicated a value of 10.5 seconds for the current lot number 564667. 2. Observation of the Sysmex CA-600 coagulation analyzer, at 7:47 a.m. on 03/03/26, revealed a patient normal mean of 10.6 seconds used for calculating patient INRs. 3. During interview at approximately 1:00 p.m. on 03/03/26, a technical consultant (#1) stated the laboratory did not enter the patient normal mean of 10.5 seconds established for the current lot number of reagent started in January 2025. 4. Reviewed on 03/03/26, the undated document titled "Quality Corner Coagulation System Validation," stated, ". . . Since the INR calculation is logarithmic, a very small error in data entry is magnified exponentially. This makes the correct input of the manufacturer's ISI (International Sensitivity Index) and the patient normal mean into the coagulation analyzer critical for patient safety. . . ."