Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	35D0409242	03/31/2026
Name of Provider or Supplier	**Street Address, City, State**	
Trinity Kenmare Hospital Dba Kenmare Comm Hospital	317 1st Ave Nw, Kenmare, 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
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) (c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (c)(1) Identity and when significant, titer, strength or concentration. (c)(2) Storage requirements. (c)(3) Preparation and expiration dates. (c)(4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: Based on observation and staff interview, the laboratory failed to label 2 of 2 hematology staining containers (Camco Quik Stain II and deionized water) observed. The laboratory performed 7 patient hematology differentials in 2025. Findings include: 1. Observation at 8:42 a.m. on 03/31/26 showed two filled containers in a sink at the hematology bench with no identifying information. 2. During interview the morning of 03/31/26, a general supervisor (#1) stated the containers in the hematology sink contained hematology staining solutions used for patient testing and confirmed the laboratory had not labeled these containers. 3. Upon request, the laboratory failed to provide a policy related to secondary reagent labeling.
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, policy review, and staff interview, the laboratory failed to

	perform required maintenance for 2 of 5 analyzers (Sysmex CA 620 [Sysmex CA-600 Series] and Beckman Coulter DxH 520) observed. The laboratory performed 147 PT /INR (Prothrombin Time/International Normalized Ratio) and 1,444 CBC (complete blood count) patient tests in 2025. Findings include: 1. Reviewed at 11:31 a.m. on 03 /31/26, the Sysmex CA-600 Series Operator's Maintenance Checklist showed the quarterly maintenance "Perform LED Cal (calibration)". 2. Reviewed the morning of 03/31/26, the January 2025 and October 2025 maintenance checklists for the Sysmex CA-600 series lacked evidence of the quarterly "Perform LED Cal" maintenance performance. 3. Reviewed on 03/31/26, the policy "Prothrombin Time Test (PT) - Sysmex CA620," dated 03/2025, stated, ". . . Quarterly Maintenance 1. LED Calibration - LED Auto-calibration . . . every 90 days . . . Refer to the Calibration section for procedure . . ." 4. Reviewed at 11:50 a.m. on 03/31/26, the DxH 520 Maintenance Log showed the yearly maintenance "Lubricating Pistons" and "Replacing Head O-Ring." 5. Reviewed the morning of 03/31/26, the January 2025 through December 2025 maintenance logs for the Beckman Coulter DxH 520 lacked evidence of the yearly "Lubricating Pistons" and "Replacing Head O-Ring" maintenance performance. 6. Upon request, the laboratory failed to provide a policy related to Beckman Coulter DxH 520 maintenance. 7. During an interview the morning of 03/31/26, a general supervisor (#1) confirmed the laboratory had not completed the following: - Quarterly "Perform LED Cal" maintenance on the Sysmex CA 620 in January 2025 and October 2025. - Yearly "Lubricating Pistons" and "Replacing Head O-Ring" maintenance on the Beckman Coulter DxH 520 in 2025.