

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 35D0409236	(X3) Date Survey Completed 07/15/2026
Name of Provider or Supplier St Lukes Hospital	Street Address, City, State 702 1st St Sw, Crosby, 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
D2010	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(2) (b)(2) The laboratory must test samples the same number of times that it routinely tests patient samples. This STANDARD is not met as evidenced by: Based on record review, staff interview, and policy review, the laboratory failed to test proficiency samples the same as patient samples for 2 of 3 hematology/coagulation events (2nd Event 2025 and 1st Event 2026). The laboratory performed 55 manual differentials in the past year. Findings include: 1. Review of the 2nd Event 2025 Hematology/Coagulation proficiency records, the morning of 07/15/26, indicated three testing personnel (#1, #2, and #3) documented blood cell identifications for BCI-06, BCI-07, BCI-08, BCI-09, and BCI-10 on 07/11/25, before the API online and postmark due date of 07/30/25. The testing personnel and lab director had signed the attestation statement documenting staff treated the samples the same as patients. 2. Review of the 1st Event 2026 Hematology/Coagulation proficiency records, at approximately 9:56 a.m. on 07/15/26, indicated three testing personnel (#2, #3, and #4) documented blood cell identifications for BCI-01, BCI-02, BCI-03, BCI-04, and BCI-05 on 03/16/26, before the API online and postmark due date of 04/01/26. The testing personnel and lab director had signed the attestation statement documenting staff treated the samples the same as patients. 3. During an interview at 10:14 a.m. on 07/15/26, testing personnel (#3) confirmed testing personnel review blood cell identifications together prior to submitting their proficiency testing findings. Testing personnel (#3) confirmed all testing personnel would not routinely review the same patient manual differentials. 4. Reviewed the afternoon of 07/15/26, the policy "Proficiency Test", dated 05/08/14, stated, ". . . All PT (proficiency testing) samples will be examined in the same manner as patient test samples using routine methods. . . . The laboratory may not test samples with greater frequency than it routinely tests patients. . . . All personnel performing PT testing

	must sign the attestation statement that all PT samples were tested in the same manner they would test patient samples. . . ."
D5775	COMPARISON OF TEST RESULTS CFR(s): 493.1281(a)(c) (a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. This STANDARD is not met as evidenced by: Based on observation, record review, and staff interview, the laboratory failed to twice annually compare and evaluate test results using different instruments for non-waived chemistry analytes for 1 of 1 year reviewed (2025). The laboratory performed 135 Creatine Kinase Myocardial Band (CKMB), 35 D-Dimer, and 191 Troponin tests in the past year. Findings include: 1. Observation of the laboratory, beginning at 8:13 a.m. on 07/15/26, showed two Triage meters (#1 and #2) on the chemistry bench. 2. Upon request on 07/15/26, the laboratory failed to provide evidence of CK-MB, D-Dimer, and Troponin twice annual test comparisons on Triage meter #1 and Triage meter #2. 3. During interview at 8:30 a.m. on 07/15/26, testing personnel (#3) confirmed the laboratory performed CK-MB, D-Dimer, and Troponin patient testing on both Triage meter #1 and Triage meter #2 and did not perform twice-annual comparisons on Triage meter #1 and Triage meter #2. 4. The laboratory failed to provide a policy regarding twice annual comparisons if a laboratory performs the same test using different methodologies or instruments.