Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	35D0409329	07/14/2026
Name of Provider or Supplier	**Street Address, City, State**	
Tioga Medical Center	810 N Welo St, Tioga, 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 observation, record review, staff interview, and policy review, the laboratory failed to test proficiency samples the same as patient samples for 4 of 15 proficiency testing events (Chemistry Core 1st Event 2026, Chemistry Core 3rd Event 2025, Chemistry Core 2nd Event 2025, and Hematology/Coagulation 3rd Event 2025. The laboratory performed 266 free thyroxine (FT4), 525 prostate-specific antigen (PSA), 1,221 thyroid-stimulating hormone (TSH), 402 vitamin D, 6,674 white blood cell (WBC), 6,232 red blood cell (RBC), 6,712 hemoglobin (HGB), 6,262 hematocrit (HCT), 6,296 platelet (PLT), 6,171 neutrophil, 6,171 lymphocyte, 6,171 monocyte, 6,171 eosinophil, 6,171 basophil tests in the past year. Findings include: 1. Observation at approximately 8:30 a.m. on 07/14/26 showed two FREND system immunoassay analyzers on the chemistry bench, labeled FREND 1 and FREND 2. 2. During an interview at approximately 8:30 a.m. on 07/14/26, general supervisor (#3) stated the FREND analyzers both report FT4, PSA, TSH, and vitamin D results. 3. Review of the Chemistry Core 1st Event 2026 proficiency records, at approximately 9:15 a.m. on 07/14/26, indicated the laboratory tested FT4 and TSH proficiency testing samples on 01/20/26 (reported on FREND 1) and again on 01/26/26 (reported on FREND 2) before the API online and postmark due date of 02/04/26. The laboratory also tested PSA and Vitamin D proficiency testing samples on 01/21/26 (reported on FREND 1) and again on 01/27/26 (reported on FREND 2) before the API online and postmark due date of 02/04/26. The testing personnel and lab director had signed the attestation statement documenting staff treated the proficiency testing samples the same as patients. 4. Review of the Chemistry Core 3rd Event 2025 proficiency records, the morning of 07/14/26, indicated the laboratory tested FT4, PSA, TSH, and

	vitamin D proficiency testing samples on 08/21/25 (reported on FREND 2) and again on 08/29/25 (reported on FREND 1) before the API online and postmark due date of 09/09/25. The testing personnel and lab director had signed the attestation statement documenting staff treated the proficiency testing samples the same as patients. 5. Review of the Chemistry Core 2nd Event 2025 proficiency records, the morning of 07 /14/26, indicated the laboratory tested FT4, PSA, TSH, and vitamin D proficiency testing samples on 05/13/25 (reported on FREND 1) and again on 05/21/25 (reported on FREND 2) before the API online and postmark due date of 05/28/25. The testing personnel and lab director had signed the attestation statement documenting staff treated the proficiency testing samples the same as patients. 6. During an interview at 10:18 a.m. on 07/14/26, general supervisor (#3) confirmed the laboratory would not routinely repeat all patient FT4, PSA, TSH, and vitamin D samples on both FREND analyzers. 7. Review of the Hematology/Coagulation 3rd Event 2025 proficiency records, at 12:16 p.m. on 07/14/26, indicated the laboratory tested WBC, RBC, HGB, HCT, PLT, neutrophil, lymphocyte, monocyte, eosinophil, and basophil proficiency testing samples on 11/05/25 and again on 11/07/25 before the API online and postmark due date of 11/18/25. The testing personnel and lab director had signed the attestation statement documenting staff treated the samples the same as patients. 8. During an interview at 1:58 p.m. on 07/14/26, general supervisor (#3) confirmed the laboratory would not routinely repeat all patient WBC, RBC, HGB, HCT, PLT, neutrophil, lymphocyte, monocyte, eosinophil, and basophil tests. 9. Reviewed the afternoon of 07/14/26, the undated policy "Proficiency Testing", stated, ". . . Test the samples as you would a patient sample . . ."
D6029	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(11) (e)(11) Ensure that prior to testing patients specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results; This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory director failed to ensure 2 of 3 testing personnel (Testing Personnel #1 and #2) received appropriate training and demonstrated reliable testing performance before reporting patient results on a new coagulation analyzer (Sysmex CA620) in July 2024 and a new erythrocyte sedimentation rate (ESR) analyzer (Alcor miniiSED) in June 2025. Findings include: 1. Reviewed at 8:42 a.m. on 07/14/26, the testing personnel records failed to include documentation of appropriate training and demonstration of reliable testing performance for Testing Personnel #1 and #2 before reporting patient results on the Sysmex CA620 and Alcor miniiSED ESR analyzers. 2. Reviewed at 4:18 p.m. on 07 /14/26, the July 2024 verification of performance specifications records for the Sysmex CA620 analyzer failed to include documentation of appropriate training and demonstration of reliable testing performance for Testing Personnel #1 and #2. 3. Reviewed at 4:52 p.m. on 07/14/26, the June 2025 verification of performance specifications records for the Alcor miniiSED analyzer failed to include documentation of appropriate training and demonstration of reliable testing performance for Testing Personnel #1 and #2. 4. Upon request on 07/14/26, the laboratory failed to provide evidence of training for Testing Personnel #1 and #2 for the Sysmex CA620 and Alcor miniiSED analyzers. 5. During interviews on 07/14/26, the general supervisor (#3) stated Testing Personnel #1 and #2 had performed patient

	testing on the Sysmex CA620 and Alcor miniiSED and confirmed the laboratory had not documented training for Testing Personnel #1 and #2 on the Sysmex CA620 and Alcor miniiSED. 6. The laboratory failed to provide a policy regarding initial training of testing personnel.