Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	35D0408659	09/11/2024
Name of Provider or Supplier	**Street Address, City, State**	
Towner County Medical Center	228 1st Ave, Cando, 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
D5551	IMMUNOHEMATOLOGY CFR(s): 493.1271(a)(f) (a) Patient testing. (a)(1) The laboratory must perform ABO grouping, D (Rho) typing, unexpected antibody detection, antibody identification, and compatibility testing by following the manufacturer's instructions, if provided, and as applicable, 21 CFR 606.151(a) through (e). (a)(2) The laboratory must determine ABO group by concurrently testing unknown red cells with, at a minimum, anti-A and anti-B grouping reagents. For confirmation of ABO group, the unknown serum must be tested with known A1 and B red cells. (a)(3) The laboratory must determine the D (Rho) type by testing unknown red cells with anti-D (anti-Rho) blood typing reagent. (f) Documentation. The laboratory must document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: Based on record review, staff interview, and policy/procedure manual review, the laboratory failed to test patients for Immunoglobin (Ig) M compatibility for 23 of 23 patient compatibility testing days (07/23/23, 08/10/23, 08/30/23, 09/02/23, 09/15/23, 10/10/23, 11/04/23, 11/29/23, 12/18/23, 01/12/24, 01/16/24, 02/01/24, 02/15/24, 03/01/24, 03/16/24, 03/22/24, 07/04/24, 07/10/24, 07/23/24, 07/24/24, 08/02/24, 08/25/24, 09/04/24) from July 23, 2023 through September 4, 2024 since the laboratory started a new method for compatibility testing. The laboratory performed 44 patient compatibility tests with no IgM compatibility testing during this timeframe. Findings include: 1. Reviewed at 07:50 a.m. on 09/11/24, the July 6, 2023 through September 10, 2024 immunohematology patient logbook failed to include evidence the laboratory performed immediate spin compatibility testing for IgM antibodies for the following: 07/23/23 Patient #599569 - two tests, 08/10/23 Patient #1242318 - one test, 08/30/23 Patient #685145 - two tests, 09/02/23 Patient #1261031 - two tests, 09/15/23 Patient #630410 - two tests, 10/10/23 Patient #685189 - two tests, 11/04/23 Patient #195910 - two tests, 11/29/23 Patient #336918 - two tests, 12/18/23 Patient #714655 -

	two tests, 01/12/24 Patient #714655 - two tests, 01/16/24 Patient #406201 - two tests, 02/01/24 Patient #676133 - two tests, 02/15/24 Patient #105207 - two tests, 03/01/24 Patient #105207 - two tests, 03/16/24 Patient #356908 - two tests, 03/22/24 Patient #1240085 - two tests, 07/04/24 Patient #150908 - two tests, 07/10/24 Patient #105207 - two tests, 07/23/24 Patient #1268173 - two tests, 07/24/24 Patient #1268173 - one test, 08/02/24 Patient #131339 - two tests, 08/25/24 Patient #525402 - two tests, and 09/04/24 Patient #105207 - two tests. 2. During interview at 8:25 a.m. on 09/11/24, a technical supervisor (#1) stated the following: the laboratory began using a new method for immunohematology patient testing on 07/06/23; the laboratory was unaware they should perform immediate spin crossmatch tests for IgM antibodies for all patient compatibility testing; and the laboratory did not perform immediate spin crossmatches for the above listed patient tests. 3. Upon review on 09/11/24, the immunohematology policy/procedure manual failed to include a policy/procedure for performing immediate spin crossmatch tests for IgM antibodies for patient compatibility testing using the new test method.