Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	35D0408554	08/03/2022
Name of Provider or Supplier	**Street Address, City, State**	
Pembina County Memorial Hospital	301 Mountain St E, Cavalier, 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
D2016	SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c) (a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history. This CONDITION is not met as evidenced by: Based on Wisconsin State Laboratory of Hygiene proficiency testing record review and staff interview, the laboratory failed to achieve satisfactory performance in proficiency testing for the analyte compatibility for two consecutive events in 2022 (Events 1 and 2), resulting in unsuccessful performance. (Refer to D2181)
D2181	COMPATIBILITY TESTING CFR(s): 493.863(e) Failure to achieve an overall testing event score of satisfactory for two consecutive

	testing events or two out of three consecutive testing events is unsuccessful performance. This STANDARD is not met as evidenced by: Based on proficiency testing record review and staff interview, the laboratory failed to achieve satisfactory performance in proficiency testing for the analyte compatibility in two of three consecutive events in 2022 (Events 1 and 2), resulting in unsuccessful performance. Findings include: 1. Review of 2022 Wisconsin State Laboratory of Hygiene (WSLH) proficiency testing reports on 08/02/22 for the analyte compatibility revealed the following results: Event 1-2022 - 20% Sample Lab Results Acceptable Results #1 not compatible compatible #2 not compatible compatible #3 not compatible compatible #4 not compatible compatible #5 not compatible not compatible Event 2-2022 - 80% Sample Lab Results Acceptable Results #6 not compatible not compatible #7 not compatible compatible #8 not compatible not compatible #9 not compatible not compatible #10 compatible compatible The analyte compatibility requires a score of 100% or greater for satisfactory performance. 2. During interview at 4:30 p.m. on 08/02/22, the laboratory manager (#1) confirmed the laboratory had scored less than 100% for compatibility in Events 1 and 2 in 2022.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document 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 observation, record review, and staff interview, the laboratory failed to perform required weekly and monthly maintenance on the Vitros XT 3400 chemistry analyzer for 1 of 1 month (July 2022) reviewed. Findings include: 1. Observed at 11: 00 a.m. on 08/03/22, the Vitros XT 3400 analyzer maintenance module, showed the following requirements: "Periodic Maintenance - Weekly W 1. Clean Tip Sealer W 2. Clean Sample Supply W 3.Clean Tip Locator W 4. Clean Dispense Blade and Sensors W 5. Clean Leak Pad W 6. Clean touchscreen monitor and keyboard W 7. Process Vitros MicorSensor Check Fluids I and II Periodic Maintenance - Monthly M 1. Clean PM Discard Chute M 2. Clean/Replace PM Evaporation Caps M 3. Clean PM Incubator Slot and Insert Blade Channels M 4. Clean MicroSensor Cover M 5. Perform System Backup . . ." 2. Reviewed at 11:00 a.m. on 08/03/22, the July 2022 maintenance records for the Vitros XT 3400 chemistry analyzer lacked evidence of weekly and monthly maintenance performance. 3. During interview at 11:10 a.m. on 08/03/22, the laboratory manager (#1) confirmed the laboratory had not documented the performance of weekly and monthly maintenance in July 2022 for the Vitros XT 3400. 4. Reviewed on 08/03/22, the undated manufacturer's maintenance record forms for the Vitros XT 3400 from "Ortho Clinical Diagnostics document: Pub. No. J64191_EN_US Version 2.0" stated, "Weekly Maintenance Log . . . Clean Tip Sealer . . . Clean Sample Supply . . . Clean Tip Locator . . . Clean Dispense Blade and Sensors . . . Clean Leak Pad . . . Clean touchscreen monitor and keyboard . . . Process Vitros MicorSensor Check Fluids I and II . . . Monthly Maintenance Log . . . Clean PM Discard Chute . . . Clean/Replace PM Evaporation Caps . . . Clean PM Incubator Slot and Insert Blade Channels . . . Clean MicroSensor Cover . . . Perform System Backup . . ."

D5451	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(iii)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Test procedures producing graded or titered results include a negative control material and a control material with graded or titered reactivity, respectively; 493.1256 (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on record review, procedure review, and staff interview, the laboratory failed to ensure documentation of A1 and B cell (reverse blood type) quality control (QC) testing 2 of 6 immunohematology patient testing days (05/23 and 06/20) in May-July 2022. The laboratory performed A1 and B cell testing for two patients on 05/23/22 and 06/20/22. Findings include: 1. Reviewed at 7:30 a.m. on 08/03/22, the May-July 2022 immunohematology patient testing and QC records indicated the laboratory performed A1 and B cell patient testing and failed to document the positive and negative A1 and B cell QC for the following: 05/23/22 Patient #610968 06/20/22 Patient #694385 2. Reviewed on 08/03/22, the procedure "MTS Gel Daily Reagent and Gel Card Quality Control," effective 02/12/13, stated, "Purpose: The purpose of daily quality control (QC) in the blood bank is to confirm the reliability of the test system. . . . Policy: 1. Gel System testing includes Ig [immunoglobulin]G Antibody Detection testing using Screening Cells, Panel Cells or Reverse A1 and B cells. 2. Gel System Quality Control for Antibody Detection Tests is completed each day (24 hours) of patient testing. 3. Gel QC results are reviewed for acceptability before reporting out patient results. . . . 3. During interview at 9:50 a.m. on 08/03/22, the laboratory manager (#1) confirmed the laboratory should perform positive and negative A1 and B cell QC each day of patient testing, and the laboratory did not document performance of positive and negative A1 and B cell QC on two patient testing days in May and June 2022.
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, procedure review, and staff interview, the laboratory failed to ensure documentation of Immunoglobulin (Ig) M compatibility on 3 of 5 patient compatibility testing days (06/23, 07/09, and 07/29) from May-July 2022. The laboratory performed five patient tests with no IgM compatibility documentation from

	May-July 2022. Findings include: 1. Reviewed at 7:30 a.m. on 08/03/22, the May-July 2022 immunohematology patient logbook failed to include evidence the laboratory performed compatibility testing for IgM antibodies when the antibody screen was negative for the following: 06/23/22 Patient #314787 - one test 07/09/22 Patient #419695 - two tests 07/29/22 Patient #496856 - two tests 2. Reviewed on 05/10/22, the procedure "Immediate Spin Cross Match - MTS Gel Method," effective 02/07/11, stated, "Principle: . . . If no clinically significant antibodies were detected in antibody screen test and there is no record of previous detection of such antibodies or no discrepancy in ABORH [blood group and Rhesus factor] typing, then only serological testing to detect ABO incompatibility is required. Pretransfusion immediate spin compatibility testing combines a potential recipient's serum with RBC [red blood cell] from an intended donor to ensure the recipient and the donor are ABO compatible. Immediate spin cross match testing is performed when the antibody screen is negative. . . ." 3. During interview at 9:50 a.m. on 08/03/22, the laboratory manager (#1) confirmed the laboratory should perform immediate spin crossmatch tests for all patient compatibility testing, and the laboratory did not document performance of an immediate spin crossmatch for the above listed patient tests.
D6076	LABORATORY DIRECTOR CFR(s): 493.1441 The laboratory must have a director who meets the qualification requirements of 493. 1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart. This CONDITION is not met as evidenced by: Based on observation, record review, procedure review, and staff interview, the laboratory director failed to fulfill the responsibility for overall operation of the laboratory regarding the maintenance of a quality assessment program (refer to D6094).
D6094	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on observation, record review, procedure review, and staff interview, the laboratory director failed to ensure the maintenance of a quality assessment program to ensure satisfactory performance in proficiency testing (refer to D2181); maintenance performance (refer to D5429); documentation of immunohematology quality control (refer to D5451); and documentation of patient compatibility testing (refer to D5551). Findings include: 1. The laboratory failed to achieve satisfactory performance in proficiency testing for the analyte compatibility in Events 1 and 2 in 2022 resulting in unsuccessful performance (refer to D2181). 2. The laboratory failed to perform required weekly and monthly maintenance on the Vitros XT 3400 chemistry analyzer in July 2022 (refer to D5429). 3. The laboratory failed to ensure documentation of A1 and B cell (reverse blood type) quality control testing on two immunohematology patient testing days in May-July 2022 (refer to D5451). 4. The

	laboratory failed to ensure documentation of Immunoglobulin M compatibility testing on three patient testing days from May-July 2022 (refer to D5551).