Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	35D0408554	09/16/2026
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
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) (b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods. This STANDARD is not met as evidenced by: Based on record review, staff interview, and policy review, the laboratory failed to ensure the testing personnel signed the attestation statements for 3 of 6 proficiency testing events (Blood Gas Event 1 2026, Coag [coagulation] Event 2 2026, and Coag Event 3 2025) reviewed. The laboratory performed 17 blood gas (pH [potential of hydrogen, scale used to measure acidity or alkalinity], pO2 [partial pressure of oxygen, a measure of the amount of dissolved oxygen gas], and PCO2 [partial pressure of carbon dioxide]), 442 PT/INR [prothrombin time international normalized ratio] and 207 PTT [partial thromboplastin time] patient tests in the past year. Findings include: 1. Reviewed at 5:46 p.m. on 09/15/26, the Blood Gas Event 1 2026 lacked evidence the testing personnel signed the proficiency testing attestation statements. 2. Reviewed at 7:50 a.m. on 09/16/26, the Coag Event 2 2026 and Coag Event 3 2025 lacked evidence the testing personnel signed the proficiency testing attestation statements. 3. During an interview at 9:55 a.m. on 09/16/26, a Laboratory Manager (#1) confirmed the testing personnel had not signed the Blood Gas Event 1 2026, Coag Event 2 2026, and Coag Event 3 2025 attestation statements. 4. Reviewed on 09/16/26, the undated policy "Proficiency Testing Procedure," stated, ". . Procedure: . . . Step 5 . . . Sign attestation statement, if applicable. . . ."
D2014	TESTING OF PROFICIENCY TESTING SAMPLES (b)(6) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency

	testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to document proficiency testing results on the lipase test for 1 of 3 Chemistry events (2026 Chem /Endo/Tx2 [Chemistry/Endocrinology/Therapeutic Drugs]) reviewed. The laboratory performed 216 lipase patient tests in the past year. Findings include: 1. Reviewed the afternoon of 09/15/26, the 2026 Chem/Endo/Tx2 proficiency testing showed lipase sample CET-9 with a result of "> [greater than] 500 U/L [units per liter]". The laboratory EHR [electronic health record] for lipase sample CET-9 showed "Test Canceled." The analyzer "Results Review" for lipase sample CET-9 showed "No Result U/L". 2. During an interview at 3:38 p.m. on 09/15/26, the Laboratory Manager (#1) stated, "The [EHR] lipase test was cancelled [for proficiency testing sample CET-9] to remove the sample from the [EHR] worklist during analyzer dilution processing. . . . For patient results, the analyzer would send a diluted lipase result of >500 [U/L] to the EHR . . ." 3. The laboratory failed to provide documentation supporting the lipase result of > 500 U/L reported to Wisconsin State Laboratory of Hygiene [WSLH] proficiency testing. 4. The laboratory failed to provide a policy regarding performing proficiency testing samples in the same manner as patient specimens.
D5215	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(2) The laboratory must verify the accuracy of any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect laboratory test performance (that is, when the proficiency testing program does not obtain the agreement required for scoring as specified in subpart I of this part, or the laboratory receives a zero score for nonparticipation, or late return or results). This STANDARD is not met as evidenced by: Based on record review, staff interview, and policy review, the laboratory failed to verify the accuracy of results for 4 of 9 events (2026 Chem/Endo/Tx2 [Chemistry /Endocrinology/Therapeutic Drugs], Blood Gas Event 1 2026, Blood Gas Event 2 2025, and HemeReg [Hematology Regulated] Event 3 2025) the Wisconsin State Laboratory of Hygiene (WSLH) assigned as not graded. The laboratory performed 607 PSA [prostate-specific antigen], 17 blood gas (pH [potential of hydrogen, scale used to measure acidity or alkalinity], pO2 [partial pressure of oxygen, a measure of the amount of dissolved oxygen gas], and PCO2 [partial pressure of carbon dioxide]), and 5,274 hematocrit patient tests in the past year. Findings include: 1. Reviewed at 3: 17 p.m. on 09/15/26, the 2026 Chem/Endo/Tx2 proficiency testing showed PSA samples CS-9 and CS-10 as not graded. The laboratory failed to evaluate the not graded results in its entirety. The laboratory repeated PSA samples CS-9 and CS-10, both of which repeat samples were still not within range. The laboratory completed no additional corrective action. 2. During an interview at 4:52 p.m. on 09/15/26, a Laboratory Manager (#1) confirmed the laboratory documented no additional

	corrective actions to evaluate the 2026 Chem/Endo/Tx2 PSA not graded results. 3. Reviewed at 5:46 p.m. on 09/15/26, the Blood Gas Event 1 2026 proficiency testing showed pO2 sample BG-5 as not graded. The laboratory failed to evaluate the not graded results. 4. Reviewed the afternoon of 09/15/26, the Blood Gas Event 2 2025 proficiency testing showed pCO2 sample BG-6, pH sample BG-6, and pO2 sample BG-9 as not graded. The laboratory failed to evaluate the not graded results. 5. Reviewed at 7:50 a.m. on 09/16/26, the HemeReg Event 3 2025 proficiency testing showed hematocrit samples AF5-11 through AF5-15 as not graded. The laboratory failed to evaluate the not graded results. 6. During an interview the morning of 09/16 /26, a Laboratory Manager (#1) confirmed the laboratory failed to document review of Blood Gas Event 1 2026, Blood Gas Event 2 2025, and HemeReg Event 3 2025 not graded results. 7. Reviewed on 09/16/26, the undated policy "Proficiency Testing Procedure," stated, ". . . Ungraded Results: . . . To review ungraded results . . . Determine acceptability of results . . . If unacceptable: Follow process for unacceptable results . . ."
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: Based on record review, staff interview, and policy review, the laboratory failed to twice annually verify the accuracy of 4 of 8 non-regulated analytes (ammonia, MCH [mean corpuscular hemoglobin], MCHC [mean corpuscular hemoglobin concentration], and RDW [red cell distribution width]) in 2025. The laboratory performed 16 ammonia, 5,267 MCH, 5,267 MCHC, and 5,267 RDW patient tests in the past year. Findings include: 1. Reviewed the afternoon of 09/15/26, the Laboratory Tests Performed document provided by a Laboratory Manager (#1) listed ammonia and CBC (complete blood count) patient testing performed in the past year. 2. Reviewed at 3:07 p.m. on 09/15/26, the 2026 Chemistry-Core 2nd Event American Proficiency Institute (API) proficiency testing records showed the laboratory did not participate in proficiency testing for ammonia. 3. Reviewed at approximately 3:30 p. m. on 09/15/26, the Chemistry 2025 Event 3, Chemistry 2026 Event 1, and Chemistry 2026 Event 2 Wisconsin State Laboratory of Hygiene (WSLH) proficiency testing records showed the laboratory did not participate in proficiency testing for ammonia. 4. Reviewed at approximately 7:50 a.m. on 09/16/26, the HemeReg [Hematology Regulated] Event 2 2026, HemeReg Event 1 2026, and HemeReg Event 3 2025 proficiency testing records showed the laboratory did not participate in MCH, MCHC, and RDW proficiency testing. 5. Reviewed at 9:44 a.m. on 09/16/26, a patient CBC [complete blood count] result included MCH, MCHC, and RDW analytes. 6. Upon request on 09/16/26, the laboratory failed to provide evidence of twice annual accuracy verification for ammonia, MCH, MCHC, and RDW in 2025. 7. During interview at 9:55 a.m. on 09/16/26, a Laboratory Manager (#1) confirmed the laboratory performed ammonia, MCH, MCHC, and RDW patient testing in 2025 and did not twice annually verify the accuracy. 8. Reviewed on 09/16/26, the undated policy "Proficiency Testing," stated, ". . . Responsible Party . . . Lab Supervisor /Manager . . . 1. Identifies the tests subject to PT [proficiency testing]. . . ."
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 and staff interview, the laboratory failed to perform required weekly and quarterly maintenance on the Sysmex CA600 coagulation analyzer and monthly maintenance on the Tosoh AIA-900 immunoassay analyzer for 8 of 8 months (January 2026 through August 2026) reviewed. The laboratory performed 442 PT /INR [prothrombin time international normalized ratio], 207 PTT [partial thromboplastin time], 607 PSA [prostate-specific antigen] and 1,488 TSH [thyroid stimulating hormone] patient tests in the past year. Findings include: 1. Reviewed at 10:54 a.m. on 09/16/26, the January 2026 through August 2026 maintenance records for the Sysmex CA600 coagulation analyzer lacked evidence of weekly and quarterly maintenance performance. 2. Reviewed on 09/16/26, the "Sysmex CA-600 Operator's Maintenance Checklist" stated, " Weekly Maintenance . . . Clean instrument interior /exterior . . . Quarterly Maintenance . . . Perform LED Calibration . . . Clean DI Water Rinse Bottle with Alcohol . . ." 3. During an interview at 11:25 a.m. on 09/16/26, a Laboratory Manager (#1) confirmed the laboratory had not documented the performance of weekly and quarterly maintenance from January 2026 through August 2026 for the Sysmex CA600 coagulation analyzer. 4. Reviewed at 12:54 p.m. on 09/16 /26, the January 2026 through August 2026 maintenance records for the Tosoh AIA-900 immunoassay analyzer lacked evidence of monthly maintenance performance. 5. Reviewed on 09/16/26, the "Tosoh AIA-900 Maintenance Log" stated, ". . . Monthly . . . Clean sample area with 70% ethanol or 70% isopropyl alcohol . . . Replace B/F [buffer/final] wash probe tips . . . Replace wash/diluent reservoir filters . . . " 6. During an interview at 1:19 p.m. on 09/16/26, a Laboratory Manager (#1) confirmed the laboratory had not documented the performance of monthly maintenance from January 2026 through August 2026 for the Tosoh AIA-900 immunoassay analyzer. 7. The laboratory failed to provide a policy related to analyzer maintenance.
D5891	POSTANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1299(a) (a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess and, when indicated, correct problems identified in the postanalytic systems specified in 493.1291. This STANDARD is not met as evidenced by: Based on record review, staff interview, and policy review, the laboratory failed to monitor the postanalytic system for 1 of 1 year reviewed (2025). Findings include: 1. Reviewed at 10:18 a.m. on 09/16/26, the 2025 quality assessment records lacked evidence of postanalytic system monitoring. 2. During interview at 10:28 a.m. on 09 /16/26, the Laboratory Manager (#1) confirmed the laboratory had not performed postanalytic monitoring in 2025. 3. Reviewed on 09/16/26, the undated policy "Quality Assurance and Improvement" stated, ". . . Laboratory must include studies that include, both pre & post analytical studies, along with analyticals. . . ."
D6086	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(3)(ii)

	(e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method; and This STANDARD is not met as evidenced by: Based on record review and staff interview, the Laboratory Director failed to evaluate and approve performance verification procedures for 1 of 1 newly implemented analyzer (Sysmex XN550) in 2025. The laboratory performed 31,602 complete blood count (CBC) patient tests since implementation of the new analyzer. Findings include: 1. Reviewed at 11:27 a.m. on 09/16/26, the Sysmex verification binder consisted of raw data for accuracy and precision. Upon request, the laboratory failed to provide evidence the Laboratory Director had evaluated and approved the performance verification data for the newly implemented Sysmex XN550 hematology analyzer in 2025. 2. During interview at 1:17 p.m. on 09/16/26, a Laboratory Manager (#1) confirmed the laboratory did not have acceptable evidence the Laboratory Director had evaluated and approved the performance verification data for the newly implemented Sysmex XN550 hematology analyzer. 3. Upon request, the laboratory failed to provide a policy related to new analyzer performance verification.
D6125	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(8)(v) (b)(8)(v) Assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples; and This STANDARD is not met as evidenced by: Based on review of competency records and staff interview, the Technical Supervisor failed to ensure 2 of 6 Testing Personnel (#2 and #3) performed an assessment of test performance through previously analyzed specimens, internal blind testing samples, or external proficiency testing samples. Findings include: 1. Reviewed at 7:47 a.m. on 09/16/26, the Annual PCMH [Pembina County Memorial Hospital] Laboratory Personnel Competency Assessments for Testing Personnel (#2 and #3) stated, ". . . 10. Participates in proficiency testing - Do not require weekend staff to participate. . . ." 2. During an interview at 1:00 p.m. on 09/16/26, a Laboratory Manager (#1) confirmed Testing Personnel (#2 and #3) did not perform proficiency testing during their annual competencies. 3. The laboratory failed to provide a policy related to competency assessment of test performance through previously analyzed specimens, internal blind testing samples, or external proficiency testing samples.
D6151	GENERAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1463(b)(3)(4) (b)(3) Providing orientation to all testing personnel; and (b)(4) Evaluating and documenting the competency of all testing personnel. This STANDARD is not met as evidenced by: Based on record review and staff interview, the General Supervisor failed to ensure proper documentation that 6 of 6 testing personnel (Testing Personnel #1, #2, #3, #4, #5, and #6) received appropriate training and demonstrated reliable performance of all testing operations before reporting patient results. Failure to ensure proper documentation for training of testing personnel limited the laboratory's ability to

	ensure testing personnel performed patient tests correctly to produce accurate and reliable results. Findings include: 1. Reviewed at 7:47 a.m. on 09/16/26, the testing personnel records failed to include documentation ensuring appropriate training and demonstration of reliable performance of all testing operations before reporting patient results on the Sysmex XS1000i (hematology analyzer), Vitros 3400 (chemistry analyzer), manual differentials (cell count and morphology of blood smears), Tosoh AIA900 (immunoassay analyzer), urine sediments (microscopic urine analysis), Sysmex CA600 (coagulation analyzer), Triage Meter Pro (immunoassay analyzer), ABO/Rh (blood typing), antibody screens (detection of red blood cell antibodies), compatibility testing (detection of incompatible units), Opti (blood gas analyzer), serum pregnancy (hCG), wet prep, and post vasectomy for Testing Personnel #6. 2. Reviewed at 11:27 a.m. on 09/16/26, the raw data provided for the verification of new tests completed October 2025 and testing personnel records failed to include documentation ensuring appropriate training and demonstration of reliable performance of all testing operations before reporting patient results on the Sysmex XN550 for Testing Personnel #1, #2, #3, #4, #5, and #6. 3. Reviewed at 12:31 p.m. on 09/16/26, the verification of new tests approved 05/28/26 and testing personnel records failed to include documentation ensuring appropriate training and demonstration of reliable performance of all testing operations before reporting patient results on the iSTAT for Testing Personnel #1, #2, #3, #4, #5, and #6. 4. Reviewed the morning on 09/16/26, the competency documentation showed the following patient testing start dates: - Testing Personnel #1 - June 1999 - Testing Personnel #2 - March 2015 - Testing Personnel #3 - October 2012 - Testing Personnel #4 - January 2016 - Testing Personnel #5 - September 2023 - Testing Personnel #6 - September 2024 5. Upon request, the laboratory failed to provide documentation of training for Testing Personnel #1, #2, #3, #4, #5, and #6. 6. During an interview the afternoon of 09/16/26, a Laboratory Manager (#1) confirmed the laboratory did not complete documentation of training on the Sysmex XN550 and iSTAT. 7. Upon request, the laboratory failed to provide a policy related to training of testing personnel.