Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	35D0408554	06/06/2018
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) 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 laboratory director and/or testing personnel signed the attestation statements for 18 of 18 (2-2017, 3-2017, and 1-2018 for bacteriology, aterial blood gases, coagulation/hematology, cardiac markers, blood banking, and chemistry /endocrinology/toxicology) proficiency testing events reviewed from the second event 2017 through the first event 2018. Findings include: 1. Reviewed at 1:45 p.m. on 06/05 /18, the second event 2017 through the first event 2018 proficiency testing records lacked evidence the laboratory director or qualified designee signed the proficiency testing attestation statements for the following eighteen events: 2-2017, 3-2017, and 1-2018 for bacteriology, aterial blood gases, coagulation/hematology, cardiac markers, blood banking, and chemistry/endocrinology/toxicology. These records lacked evidence the testing personnel signed the proficiency testing attestation statements for the following three events: 2-2017 blood banking, 1-2018 bacteriology, and 1-2018 cardiac markers. 2. During an interview at 4:20 p.m. on 06/05/18, a general supervisor (#1) confirmed the laboratory director or qualified designee and/or testing personnel had not signed the eighteen proficiency testing attestation statements listed above. 3. Reviewed at 11:30 a.m. on 06/06/18, the undated policy "0610.01 Proficiency Testing Procedure," stated, ". . . Procedure: . . . Step 5 . . . Sign attestation statement, if applicable. . . ."
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 and staff interview, the laboratory failed to twice annually verify the accuracy of 1 of 3 non-regulated microscopy analytes (sperm absence /presence) in 2017. The laboratory performed two patient tests for sperm absence /presence in 2017. Findings include: 1. Reviewed at approximately 1:40 p.m. on 06/05 /18, the laboratory's test menu listed post vas semen analysis (sperm absence /presence) available for patient testing. 2. Reviewed at approximately 1:45 p.m. on 06 /05/18, the 2017 proficiency testing records indicated the laboratory did not participate in proficiency testing for sperm absence/presence. 3. Upon request on 06/06 /18, the laboratory failed to provide evidence of twice annual accuracy verification for sperm absence/presence in 2017. 4. During interview at approximately 10:45 a.m. on 06/06/18, a general supervisor (#1) confirmed the laboratory performed post vas semen analysis (sperm absence/presence) patient testing in 2017 and did not twice annually verify the accuracy. 5. Upon request on 06/06/18, the laboratory failed to provide a policy requiring twice annual accuracy verification for post vas semen analysis (sperm absence/presence).
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to verify calibration for 4 of 7 analytes (CK-MB [creatine kinase-muscle and brain subunits], troponin, myoglobin, and Prostate Specific Antigen [PSA]) calibrated with less than three calibrators at least once every six months in 2017. Findings include: 1. Reviewed at approximately 4:45 p.m. on 06/05/18, the 2017-2018 calibration records indicated the laboratory used less than three levels of calibrator to calibrate CK-MB, troponin, and

	myoglobin on the Biosite Triage Meter Plus chemistry analyzer. 2. Reviewed at approximately 4:50 p.m. on 06/05/18, the 2017 calibration verification records lacked evidence the laboratory verified calibration of CK-MB, troponin, and myoglobin in 2017. 3. Reviewed at approximately 10:35 a.m. on 06/06/18, the 2017-2018 calibration records indicated the laboratory used less than three levels of calibrator to calibrate PSA on the TOSOH chemistry analyzer. 4. Reviewed at approximately 10: 40 a.m. on 06/06/18, the 2017 calibration verification records lacked evidence the laboratory verified calibration of PSA the first six months of 2017. 5. During interview at approximately 10:45 a.m. on 06/06/18, a general supervisor (#1) confirmed the laboratory did not perform calibration verification at least once every six months for PSA, CK-MB, troponin, and myoglobin in 2017. 6. Upon request on 06 /06/18, the laboratory failed to provide a policy requiring calibration verification at least once every six months.
D5449	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(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-- Each qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on record review, staff interview, and policy review, the laboratory failed to perform a positive and negative control each day of patient testing for 3 of 3 patient testing days in May 2018 (05/03, 05/07, and 05/09) for serum pregnancy. The laboratory performed five serum pregnancy patient tests during this timeframe. Findings include: 1. Reviewed at 5:05 p.m. on 06/05/18, the May 2018 serum pregnancy quality control (QC) records lacked evidence the laboratory performed a negative and positive control on three patient testing days (05/03, 05/07, and 05/09). 2. During interview at approximately 5:10 p.m. on 06/05/18, a general supervisor (#1) stated the laboratory should perform positive and negative external QC each day of patient testing and failed to on 05/03/18, 05/07/18, and 05/09/18. 3. Reviewed on 06 /06/18, the policy "Quality Control Frequency and QC Material," dated 05/23/06, stated, ". . . Qualitative Pregnancy Once per lot . . ." The policy failed to require QC performance each day of patient testing for qualitative serum pregnancy.
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, staff interview, and policy review, the laboratory failed to perform quality control (QC) testing each day of immunohematologic patient testing

	for 2 of 8 patient testing days in February-March 2018 (02/01/18 and 03/06/18). Findings include: 1. Reviewed at approximately 7:30 a.m. on 06/06/18, the February-March 2018 patient testing and QC records indicated the laboratory did not perform QC on the following immunohematologic patient testing days: 02/01/18 Patient #53848 - Blood type and antibody screen 03/06/18 Patient #1063755 - Blood type 2. During interview at approximately 8:55 a.m. on 06/06/18, a general supervisor (#1) confirmed the laboratory did not document results of QC testing on 02/01/18 and 03 /06/18. 3. Review of the laboratory's immunohematologic policies occurred at 9:00 a. m. on 06/06/18. The policy "ABO and RH Testing Patient Samples Using MTS [Micro Typing Systems] Gel Method," dated 02/07/11, stated, ". . . Quality Control: Quality Control will be performed each day (24 hours) patient samples are to be tested. . . ." The policy "Gel IGG [Immunoglobulin G] Antibody Screen Testing," dated 02/07/11, stated, ". . . Quality Control: 1. Gel Card - To confirm the specificity and reactivity of the MTS Anti-IgG Card each lot is tested on each day of use with known positive and negative antibody samples with the appropriate red blood cells. . . ."
D5471	CONTROL PROCEDURES CFR(s): 493.1256(e)(1)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e)(i) Check each batch (prepared in-house), lot number (commercially prepared) and shipment of reagents, disks, stains, antisera, (except those specifically referenced in 493.1261 (a)(3)) and identification systems (systems using two or more substrates or two or more reagents, or a combination) when prepared or opened for positive and negative reactivity, as well as graded reactivity, if applicable. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on observation, staff interview, and policy review, the laboratory failed to perform quality control (QC) for 1 of 1 microbiology reagents (potassium hydroxide [KOH]) before use. The laboratory performed approximately 50 patient tests using KOH reagent in 2017. Findings include: 1. Observation of the laboratory on 06/06/18 at approximately 10:55 a.m. revealed KOH reagent, lot number 1711407, available for patient testing. 2. Upon request at approximately 10:55 a.m. on 06/06/18, the laboratory failed to provide evidence of performing QC for KOH reagent lot number 1711407. 3. During interview at approximately 10:55 a.m. on 06/06/18, a general supervisor (#1) confirmed the laboratory had used KOH reagent for patient testing and had not performed QC on the KOH reagent. 4. Reviewed on 06/06/18, the policy "Quality Control Frequency and QC Material," dated 05/23/06, failed to include QC requirements for KOH reagent.
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 review, the laboratory failed to test patients for Immunoglobin (Ig) M compatibility for 6 of 6 compatibility tests (2 on 09/23/17, 2 on 09/26/17, and 2 on 01/31/18) performed for Patient #258692 in September 2017 and January 2018. Findings include: 1. Reviewed at approximately 7: 30 a.m. on 06/06/18, the test records for Patient #258692 indicated the laboratory did not perform IgM (ABO) compatibility testing for 2 units on 09/23/17, 2 units on 09/26 /17, and 2 units on 01/31/18. 2. During interview at approximately 8:55 a.m. on 06/06 /18, a general supervisor (#1) confirmed the laboratory did not document results of immediate spin compatibility testing for Patient #258692. 3. Reviewed at 9:00 a.m. on 06/06/18, the policy "Immediate Spin Cross Match MTS [Micro Typing Systems] Gel Method," dated 02/07/11, stated, "Principle: . . . Pretransfusion immediate spin compatibility testing combines a potential recipient's serum with RBC from an intended donor to ensure the recipient and the donor are ABO compatible. . . ."