Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	35D0408554	01/27/2021
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
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(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-- (d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on policy review, record review, and staff interview, the laboratory failed to perform quality control (QC) as stated in their policy for 3 of 3 tests (troponin, creatine kinase-myocardial band [CK-MB], and myoglobin) with Individual Quality Control Plans (IQCPs). The laboratory performed approximately 350 patient tests for troponin, CK-MB, and myoglobin in March, July, August, and October 2020 when the laboratory failed to perform monthly QC. Findings include: 1. Reviewed at 9:30 a.m. on 01/27/21, the IQCP for Biosite Triage (including troponin, CK-MB, and myoglobin), approved 7/14/16, stated, ". . . Final QCP [quality control plan] for Biosite Triage Based on the IQCP, assessment we feel that monthly QC or with each new shipment, whichever is more frequent will be satisfactory for our facility. . . ." 2. Review of the 2020 Biosite Triage QC records indicated the laboratory failed to perform external QC monthly for troponin, CK-MB, and myoglobin during the following months: March, July, August, and October. 3. Upon request on 01/27/21, the laboratory failed to provide additional evidence of external QC performance for the Biosite Triage tests in March, July, August, and October 2020. 4. During interview at 9:50 a.m. on 01/27/21, the laboratory supervisor (#1) confirmed the laboratory expected monthly external QC performance on the Biosite Triage tests, and the

	laboratory did not have evidence of external QC for troponin, CK-MB, and myoglobin during March, July, August, and October 2020.
D5891	POSTANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1299(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, policy review, and staff interview, the laboratory failed to monitor the postanalytic system for 1 of 1 year reviewed (2020). Findings include: 1. Reviewed at 4:15 p.m. on 01/26/21, the 2020 quality assessment records lacked evidence of postanalytic system monitoring in 2020. 2. Reviewed on 01/26/21, the undated policy "Quality Assurance and Improvement" stated, ". . . Purpose 2. Shall be an ongoing project . . . encompassing all areas of laboratory function. . . ." 3. During interview at 10:00 a.m. on 01/27/21, the laboratory supervisor (#1) confirmed the laboratory had not performed postanalytic monitoring in 2020.
D6087	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(3)(iii) The laboratory director must ensure that laboratory personnel are performing the test methods as required for accurate and reliable results. This STANDARD is not met as evidenced by: Based on observation, record review, staff interview, and manufacturer's instructions review, the laboratory failed to use the correct mean normal protime (PT) value for calculating International Normalized Ratios (INRs) for 13 of 13 days (January 15-27, 2021) since the laboratory began using a new lot number of innovin reagent on their coagulation analyzer. The laboratory performed approximately 14 tests during this timeframe. Findings include: 1. Observation of the Sysmex CA-600 coagulation analyzer at 9:50 a.m. on 01/27/21 revealed a mean normal PT value of 9.9 used to calculate patient INRs. 2. Reviewed at 9:55 a.m. on 01/27/21, the undated data used to determine the mean normal PT for the new lot number of innovin reagent lacked evidence the laboratory calculated the value of the mean normal PT. 3. During interview at 9:55 a.m. on 01/27/21, the laboratory supervisor (#1) confirmed the laboratory started using the new lot number of innovin reagent for patient testing on 01 /15/21. The laboratory supervisor (#1) confirmed the laboratory did not have evidence of the mean normal PT calculation using the new lot number of innovin and confirmed 9.9 would not be an accurate value for the data collected using the new lot number of innovin. 4. Reviewed on 01/27/21, the Siemens CA-600 operator's instructions, dated 01/2013, stated, "XIV. Reagent Lot Roll-Over Studies . . . I. Verification of the Reference Range A. 20 Normal Individuals B. Assay samples on . . . new lot number reagents . . . C. Calculate mean . . . D. MNPT [Mean Normal PT] for INR calculation must be the geometric mean. . . . To 'go live' with the new lot numbers, follow these steps: . . . 2. Input the new . . . Mean Normal PT: . . . - Use the mean normal PT obtained from a minimum of 20 normal samples tested on new lot of reagent. . . ."

D6120	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(7)(8) (7) The technical supervisor is responsible for identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed; (8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. This STANDARD is not met as evidenced by: Based on record review, policy review, and staff interview, the technical supervisor failed to include immunohematological testing in the annual competency evaluations for 8 of 8 sampled testing personnel (#1 - #8) in 2020. Findings include: 1. Reviewed at 3:15 p.m. on 01/26/21, the 2020 competency evaluation records for Testing Personnel #1 - #8 lacked evidence of completed competency evaluations for immunohematological testing (blood type, antibody screen, and compatibility). 2. Reviewed at 4:00 p.m. on 01/26/21, the policy "Assessment for Personnel," revised 04 /08/19, stated, "Purpose: The Clia [sic] '88 requires that the laboratory establish and maintain a mechanism to evaluate and demonstrate comptency in test performance of each person who performs a clinical diagnostic test. . . . Interval: . . . 4. Annually thereafter. . . ." 3. During interview at 8:30 a.m. on 01/27/21, the laboratory supervisor (#1) confirmed the competency evaluations for Testing Personnel #1 - #8 in 2020 did not include immunohematological testing.