Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	53D2158530	01/25/2023
Name of Provider or Supplier	**Street Address, City, State**	
North Platte Valley Medical Center	1300 W Bridge Ave, Saratoga, WY	

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 review of proficiency testing records, lack of documentation, and staff interview, the testing personnel (TP) and/or the laboratory director (LD) failed to attest to the routine integration of proficiency tests into the patient workload for 4 of 8 AAB (American Association of Bioanalysts) and 6 of 12 CAP (College of American Pathologists) proficiency testing (PT) events reviewed from September 2021 through December 2022. The findings were: 1. Review of the AAB proficiency testing records failed to include the signatures of the testing personnel (TP) and/or the laboratory director (LD) for the following events: a. The 2021 non-chemistry quarter 3 event attestation statement failed to include the signature of the LD on the serology section of the PT event. b. The 2021 chemistry quarter 3 event attestation statements failed to include the signature of the LD on the urinalysis, lipid, ammonia, clinical microscopy, D-dimer, special chemistry, immunochemistry, basic chemistry, and comprehensive chemistry sections of the PT event. In addition, the clinical microscopy attestation statement failed to include the signature of the TP. c. The 2022 chemistry quarter 1 event attestation statements failed to include the signature of the LD on the basic chemistry, clinical microscopy, comprehensive chemistry, immunochemistry, urinalysis, and special chemistry sections of the PT event. In addition, the comprehensive chemistry and urinalysis attestation statements failed to include the signature of the TP. d. The 2022 chemistry quarter 2 event attestation statements failed to include the signature of the LD on the comprehensive chemistry section of the PT event. 2. Review of the CAP proficiency testing records failed to include the signatures of the TP and/or the LD for the following events: a. The 2021 quarter 3

	diagnostic immunology attestation statement failed to include the signature of the LD. b. The 2021 quarter 2 PCT-B attestation statement failed to include the signature of the LD. c. The 2022 quarter 3 CAR-C attestation statement failed to include the signature of the LD. d. The 2022 quarter 1 K-A attestation statement failed to include the signature of the TP and the LD. e. The 2022 quarter 2 K-B attestation statement failed to include the signature of the TP and the LD. f. The 2022 quarter 1 PCT-A records failed to include a copy of the attestation statement. 3. Interview with the general supervisor on 1/25/23 at 9:45 AM confirmed the attestation statements had not been signed.
D5211	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a) The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part. This STANDARD is not met as evidenced by: Based on review of the AAB (American Association of Bioanalysts) and CAP (College of American Pathologists) proficiency testing (PT) records, lack of documentation, and staff interview, the laboratory failed to review and evaluate proficiency testing results for 6 of 20 testing events reviewed from September 2021 to December 2022. The findings were: 1. Review of the AAB and CAP proficiency testing records failed to include documentation the laboratory had evaluated the proficiency testing results. The following concerns were identified: a. Review of the AAB 2021 quarter 3 non-chemistry event showed no documentation the laboratory director (LD) had reviewed the results. b. Review of the AAB 2021 quarter 3 chemistry event showed no documentation the LD had reviewed the results. c. Review of the AAB 2022 quarter 1 chemistry event showed no documentation the LD had reviewed the results. d. Review of the CAP 2021 PCT-B (procalcitonin) event showed no documentation the LD had reviewed the results. e. Review of the CAP 2021 CAR-C (troponin I) event showed no documentation the LD had reviewed the results. f. Review of the CAP 2022 CAR-B (troponin I) event showed no documentation the LD had reviewed the results. 2. Interview with the general supervisor on 1/25/23 at 9:45 AM confirmed the PT records did not show documentation of the LD's review of the results.
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 review of proficiency testing records, lack of documentation, and staff interview, the laboratory failed to have a system in place for reviewing proficiency test results that received an artificial score of 100% due to lack of peer group data for 6 of 20 AAB (American Association of Bioanalysts) and CAP (College of American Pathologists) proficiency testing events reviewed from September 2021 to December

	2022. This failure affected the analytes of troponin I, ammonia, lipase, and D-dimer. The laboratory performed approximately 10 troponin I, 2 ammonia, 8 lipase, and 10 D-dimer patients tests annually. The findings were: 1. Review of the CAP proficiency testing evaluation forms showed the laboratory received an artificial score of 100% on the analyte of troponin I on the CAP 2021 CAR-C event, the CAP 2022 CAR-A event, and the CAP 2022 CAR-C event due to a lack of peer group data. There was no documentation the laboratory had performed a self-evaluation. 2. Review of the AAB proficiency testing evaluation forms showed the laboratory received an artificial score of 100% on the analyte of ammonia on the AAB 2022 quarter #1, quarter #2, and quarter #3 due to a lack of peer group data. There was no documentation the laboratory had performed a self-evaluation. 3. Review of the AAB 2022 quarter #2 proficiency testing evaluation form showed the laboratory received an artificial score of 100% on the analyte of lipase due to a lack of peer group data. There was no documentation the laboratory had performed a self-evaluation. 4. Review of the AAB 2022 quarter #3 proficiency testing evaluation form showed the laboratory received an artificial score of 100% on the analyte of D-dimer due to a lack of peer group data. There was no documentation the laboratory had performed a self-evaluation. 5. Interview with the general supervisor on 1/25/23 at 9:45 AM confirmed an evaluation of the proficiency testing results had not been performed to ensure the accuracy of the analytes.
D5435	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(2) For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must: (i) Define a function check protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (ii) Perform and document the function checks, including background or baseline checks, specified in paragraph (b)(2)(i) of this section. Function checks must be within the laboratory's established limits before patient testing is conducted. This STANDARD is not met as evidenced by: Based on observation, review of the Beckman Coulter Allegra X-30R centrifuge manufacturer's instructions for use, and staff interview, the laboratory failed to define a function check protocol to ensure system performance for 1 of 1 centrifuge (Beckman Coulter Allegra X-30R). The findings were: 1. Observation on 1/24/23 at 1:45 PM showed the laboratory used a Beckman Coulter Allegra X-30R centrifuge to separate blood components for patient testing. 2. Review of the Beckman Coulter Allegra X-30R centrifuge manufacturer's instructions for use showed no function check protocols were provided by the manufacturer. 3. There was no documentation the laboratory had defined a function check and maintenance protocol. 4. Interview with the general supervisor on 1/24/23 at 1:57 PM confirmed function checks on the centrifuge had not been performed.