Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 53D2158530	(X3) Date Survey Completed 09/09/2021
Name of Provider or Supplier North Platte Valley Medical Center	**Street Address, City, State** 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
D3000	FACILITY ADMINISTRATION CFR(s): 493.1100 Each laboratory that performs nonwaived testing must meet the applicable requirements under 493.1101 through 493.1105, unless HHS approves a procedure that provides equivalent quality testing as specified in Appendix C of the State Operations Manual (CMS Pub. 7). (a) Reporting of SARS-CoV-2 test results During the Public Health Emergency, as defined in 400.200 of this chapter, each laboratory that performs a test that is intended to detect SARS-CoV-2 or to diagnose a possible case of COVID-19 (hereinafter referred to as a "SARS-CoV-2 test") must report SARS-CoV-2 test results to the Secretary in such form and manner, and at such timing and frequency, as the Secretary may prescribe. This CONDITION is not met as evidenced by: Based on the laboratory's COVID-19 patient testing log, review of policy and procedure, and staff interview, the laboratory failed to report 233 SARS-CoV-2 negative test results, as required, for 15 weeks of testing (5/24/21 to 9/8/21) reviewed. The findings were: 1. Review of the laboratory's COVID-19 patient testing log showed 308 SARS-CoV-2 patient tests were performed using the Abbott Binax Now test system from 5/24/21 to 9/8/21. There was no evidence the 233 negative patient test results had been reported to the State Public Health Laboratory. 2. Review of the procedure titled "Abbot Binax Now Covid-19" showed "Positive results must be reported to the State of Wyoming Public Health Department." 3. Interview with the laboratory manager on 9/9/21 at 1:40 PM confirmed the negative patient test results were not reported to the State Public Health Laboratory.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper

	storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on review of the laboratory's environmental records, review of manufacturer's instructions, and staff interview, the laboratory failed to monitor humidity in the testing and reagent storage areas. The laboratory estimated it would perform approximately 15,095 tests annually. The findings were: 1. Review of the daily environmental log showed the humidity level in the lab was not monitored. 2. Review of the Beckman Coulter manufacturer's instructions showed the following environmental requirements: a. The Access 2, AU480, and IQ200 required the relative humidity to be maintained between 20% and 80%. b. The DxH900 required the relative humidity to be less than 70%. 3. Interview with the laboratory manager on 9/9 /21 at 9:15 AM confirmed the laboratory did not measure, monitor, or record relative humidity.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on new instrumentation and new test method verification study review, and staff interview, the laboratory failed to verify the accuracy for 4 of 4 new Beckman Coulter analyzers (AU480, Access 2, DxH900, IQ200) prior to patient testing. The laboratory estimated 10,160 routine chemistry tests, 3700 hematology tests, 675 endocrinology tests, 550 urinalysis tests, and 10 general immunology tests would be performed annually. The findings were: 1. Review of the laboratory's new instrument verification study for the Beckman Coulter AU480 (chemistry analyzer), the Beckman Coulter Access 2 immunoassay analyzer), the Beckman Coulter DxH900 (hematology analyzer), and the Beckman Coulter IQ200 (urinalysis analyzer) failed to show the performance specification of accuracy had been verified by the laboratory prior to patient testing on 5/4/21. 2. Interview with the laboratory manager on 9/9/21 at 10 AM confirmed the laboratory had not verified accuracy prior to testing patient samples.
D6013	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(ii) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform

	test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(3) Ensure that-- (e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method; This STANDARD is not met as evidenced by: Based on review of the instrumentation method verification records, lack of documentation, and staff interview, the laboratory director failed to evaluate and approve the results of the reportable range and precision verification studies and ensure the accuracy of each new analyzer prior to testing patient samples for 4 of 4 new analyzers (Access 2, AU480, DxH900, IQ200). The laboratory estimated it would perform approximately 15,095 tests annually. The findings were: 1. Review of the laboratory's new instrument verification study for the Beckman Coulter AU480 (chemistry analyzer), the Beckman Coulter Access 2 (immunoassay analyzer), the Beckman Coulter DxH900 (hematology analyzer), and the Beckman Coulter IQ200 (urinalysis analyzer) failed to show the performance specification of accuracy had been verified by the laboratory prior to patient testing on 5/4/21. 2. Review of the method verification records for the Beckman Coulter Access2, AU480, DxH900, and IQ200 showed the performance specifications for reportable range and precision had been verified, however the laboratory director had not signed the report as approved. 3. Interview with the laboratory manager on 9/9/21 at 10 AM confirmed the new instrument verification studies had not been signed by the laboratory director and the accuracy studies had not been completed.