Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	53D2158530	03/06/2025
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
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on review of personnel files, review of the Centers for Medicare and Medicaid Services 209 Laboratory Personnel Report, lack of documentation, review of policy and procedure, and staff interview, the general supervisor failed to complete a 6-month competency assessment for 1 of 2 testing personnel (TP #1) reviewed. The findings were: 1. Review of the personnel file for TP #1 showed she was hired on 2/2/24 and an initial competency assessment had been completed; however, there was no documentation a 6-month competency assessment had been performed. 2. Interview with the general supervisor on 3/5/25 at 4:35 PM revealed she had assumed the position of general supervisor in October of 2024. The 6-month competency assessment for TP #1 could not be located. 3. Review of the Personnel Requirements policy and procedure, last reviewed by the laboratory director on 1/3/22, showed "General Supervisor will conduct employee competency evaluations. An employee will be assessed every 6 months for the first year of their employment and annually every year thereafter."
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) (b) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (b)(1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (b)(1)(i)

	(A) Accuracy. (b)(1)(i)(B) Precision. (b)(1)(i)(C) Reportable range of test results for the test system. (b)(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 test method verification study review, lack of documentation, and staff interview, the laboratory failed to ensure the verification studies were complete for 1 of 2 (Medtox urine drug screen) test system prior to patient testing. The laboratory performed approximately 108 Medtox urine drug screens per year. The findings were: 1. Review of the laboratory's documentation showed no evidence a verification study for the Medtox urine drug screen test system had been completed prior to patient testing. 2. Interview with the general supervisor on 3/6/25 at 8 AM revealed she had assumed the position of the general supervisor in October 2024. The general supervisor was unable to locate the verification study; however, was able to determine patient testing began on 8/16/23. Interview with the laboratory director on 3/6/25 at 9: 04 AM revealed he recalled a verification study being performed; however, was unable to locate the documentation.
D5435	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(2) (b)(2)(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. (b)(2)(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 laboratory's documentation, and staff interview, the laboratory failed to perform function checks on each piece of equipment /instrument it uses to ensure accurate and reliable test reporting for 1 of 2 years (2024). The findings were: 1. Review of the immunohematology documentation showed the serologic centrifuge for immediate agglutination was to be calibrated annually. The method outlining the procedure was signed by the laboratory director on 6/28/23. The procedure stated it was last completed in June of 2023. There was no evidence the procedure had been completed in 2024. 2. Review of the immunohematology documentation showed the serologic centrifuge for washing and antiglobulin testing was to be calibrated annually. The method outlining the procedure was signed by the laboratory director on 6/28/23. The procedure stated it was last completed in June of 2023. There was no evidence the procedure had been completed in 2024. 3. Observation of the laboratory on 3/6/25 showed 4 pipettes were available for patient testing. Each pipette was labeled with a sticker which stated service was due on 6/27/23. 4. Review of the laboratory's documentation showed no evidence the timers or thermometers had been checked for accuracy. 5. Interview with the general supervisor on 3/6/25 at 11:43 AM confirmed no further documentation was available.
D5449	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(g) (d)(3)(ii) Each qualitative procedure, include a negative and positive control material;

	This STANDARD is not met as evidenced by: Based on lack of documentation and staff interview, the laboratory failed to perform a positive and negative control each day of patient testing for the Medtox urine drug screen test system. This failure affected approximately 108 patient tests. The findings were: 1. Review of the laboratory's quality control records showed no documentation external quality control had been performed on the Medtox urine drug screen test system. 2. Interview with the general supervisor on 3/6/25 at 10:26 AM revealed she had assumed the position of general supervisor in October of 2024. The general supervisor revealed she had recently identified the failure and had ordered external quality control. Further, the general supervisor was able to determine patient testing started on 8/16/23.
D5555	IMMUNOHEMATOLOGY CFR(s): 493.1271(c)(f) (c) Blood shall be stored in a clean and orderly environment in a manner to prevent mix-ups. Expired blood must not be in the routine inventory. Unacceptable units must be segregated from routine inventory. (c)(1) An audible alarm system must monitor proper blood and blood product storage temperature over a 24-hour period. (c)(2) Inspections of the alarm system must be documented. This STANDARD is not met as evidenced by: Based on observation, staff interview, review of the laboratory's immunohematology documentation, and policy and procedure review, the laboratory failed to ensure the audible alarm was inspected and functioning appropriately for 1 of 2 years reviewed (2024). The findings were: 1. Observation of the blood product storage refrigerator showed 1 unit of O positive and 1 unit of O negative packed red blood cells were available for patient use. 2. Review of the laboratory's immunohematology verification study showed it was completed on 5/25/23 and signed by the laboratory director on 5/30/23. 3. Review of the "Blood Bank Alarm Checks" policy, last reviewed by the laboratory director on 8/29/24, showed alarm checks were to be completed monthly to ensure the remote alarms were functioning and personnel responded in a timely manner. The set point of the alarm system was to be validated quarterly. Review of the 2024 log sheet showed the monthly alarm checks were completed in March, May, June, and July. The quarterly checks were completed in March, May, June and July. There was no evidence the blood product storage unit audible alarms had been checked in 2025. 4. Interview with the general supervisor on 3/6/25 at 10:37 AM confirmed no further documentation was available.