Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 53D0681667	**(X3) Date Survey Completed** 02/18/2026
Name of Provider or Supplier Powell Valley Healthcare	**Street Address, City, State** 777 Avenue H, Powell, 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 (CMS) 209 Laboratory Personnel Report, lack of documentation, review of policy and procedure, and staff interview, the technical/general supervisor failed to complete an initial competency assessment for serology testing for 1 of 9 testing personnel (TP #8) reviewed; failed to complete an annual competency assessment in the specialty of microbiology for 1 of 9 testing personnel (TP #7) reviewed; failed to ensure an annual competency assessment was completed for the position of general supervisor for 2 of 2 years reviewed (2024, 2025); and failed to ensure an annual competency assessment was completed for the position of technical supervisor for 1 of 2 years reviewed (2024). The findings were: 1. Review of the personnel file for TP #8 showed she was hired on 6/2/25. There was no evidence an initial competency assessment was completed for serology testing. 2. Review of the personnel file for TP #7 failed to show a competency assessment for the specialty of microbiology was completed in 2025. 3. Review of the CMS-209 Laboratory Personnel Report showed the duties of the general supervisor and technical supervisor were performed by the laboratory manager. Review of the personnel record for the laboratory showed a competency assessment was not completed for the duties of the technical supervisor in 2024. In addition, there was no evidence a competency assessment had been completed for the duties of the general supervisor in 2024 or 2025. 4. Interview with the technical supervisor on 2/18/26 at 10:48 AM confirmed no further documentation could be located. 5. Review of the "Personnel Competency Review In the Lab" policy, effective November 1996, showed "Technical Supervisor, General Supervisor,

	Medical Technologists and Phlebotomists will be given an annual competency assessment that will be reviewed by the Director of Laboratory Services or qualified designee. This list will include the knowledge and skills required to perform their job. New Employees competence will be reviewed upon start, at six months, and at one year during their first year of employment. After the first year of employment, each staff member's competency is assessment on an annual basis..."
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) (a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: Based on review of patient test reports, review of the VITROS XT 7600 analyzer manufacturer's instructions for use, and staff interview, the laboratory failed to follow the manufacturer's instructions to include the prostate specific antigen (PSA) test assay method on 1 of 1 PSA patient tests reports (patient #1) reviewed. The laboratory performed 874 PSA patient tests annually. The findings were: 1. Review of the VITROS XT 7600 analyzer manufacturer's instructions stated "Different test methods cannot be used interchangeably. PSA results in a given patient sample determined with different tests and from different manufacturers can vary due to differences in test methods and reagent specificity. A change to a different method during serial monitoring of a patient should be accompanied by additional sequential testing to confirm baseline values. The results reported by the laboratory to the physician must include the identity of the PSA test used." The following concerns were identified: a. Review of the test report for patient #1, dated 2/17/26, failed to include the PSA test methodology. 2. Interview with the technical supervisor on 2/18/26 at 12:20 PM confirmed the PSA test method was not included on the patient test report.
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 instrument and new test method verification study review, lack of documentation, review of policy and procedure, and staff interview, the laboratory failed to verify the reportable range and confirm the manufacturer's normal values were appropriate for the laboratory's patient population for 1 of 6 (VITROS XT 7600) verification studies reviewed. The findings were: 1. Review of the 5/8/24 new instrument verification study for the VITROS XT 7600 analyzer failed to show documentation the laboratory had verified the reportable range and had confirmed the

	reference intervals used for the test system were appropriate for the laboratory's population. 2. Interview with the technical supervisor on 2/18/26 at 12:20 PM confirmed no further documentation was available. In addition, the technical supervisor revealed the laboratory began using the VITROS XT 7600 analyzer on 5/13/24. 3. Review of the "Verification of Tests, methods, and Instruments" policy and procedure, effective February 2010, showed "...1. When adding or replacing a test, method, or instrument, PVHC laboratory shall verify the manufacturer's performance specifications including accuracy, precision and reportable ranges. 2. When replacing an old test, method, or instrument PVHC laboratory shall verify correlation between the old and new test, method, or instrument. 3. For each new test, method, or instrument, PVHC laboratory shall verify and establish reference ranges and QC ranges for the test, method or instrument and population served, prior to reporting patient results..."
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 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 2 of 2 blood product storage units for 1 of 2 years reviewed (2025). The findings were: 1. Review of the 2025 Blood Bank refrigerator temperature and alarm check (to be performed quarterly) log sheet showed the audible alarm was checked on 3/31/25 and 10/14/25. Review of the 2025 plasma freezer temperature and alarm check (to be done quarterly) log sheet showed the audible alarm was checked on 3/31/25, 7/20/25, and 10/14/25. 2. Interview with the technical supervisor on 2/18/26 at 3 PM confirmed the audible alarm systems on the blood and blood product storage units had not been performed as required. 3. Review of the "Plasma Freezer Alarm Checks" policy and procedure, effective June 1997, showed "The alarm system on the plasma freezer should be checked quarterly to be sure that it is functioning properly. The results of the check will be recorded on the log sheet provided for this purpose." 4. Review of the "Blood Bank Refrigerator Alarm Checks and Quarterly Maintenance" policy and procedure, effective February 2007, showed "To provide a means of checking that the alarm system on the blood bank refrigerator functions properly by testing both low and high temperature alarm activations. The alarm checks on the blood bank refrigerator should be done quarterly."