

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  53D0662169	<b>(X3) Date Survey Completed</b>  04/30/2025
<b>Name of Provider or Supplier</b>  Wyoming Public Health Laboratory	<b>Street Address, City, State</b>  208 S College Drive, Cheyenne, WY	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D0000</b>	Federal jurisdiction recertification survey with standard level deficiencies cited.
<b>D5413</b>	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p> <p>(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: (b)(1) Water quality. (b)(2) Temperature. (b)(3) Humidity. (b)(4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.</p> <p>This STANDARD is not met as evidenced by: Based on direct observation of the Serology laboratory, review of reagent and quality control package inserts, review of Serology temperature recording chart, and interviews with the Serology General Supervisor and the Quality Assurance Coordinator, the laboratory failed to ensure the storage temperature ranges were within the manufacturer's specifications for storage for 40 of 40 boxes of Diasorin test reagents and 22 of 22 Diasorin quality control kits used with the Liaison XL instrument located in room number 1398. Findings included: 1. An observation during a tour of the laboratory, room number 1398, on 04/30/2025 at 9:10 AM, revealed the following Diasorin items stored in the VWR refrigerator (serial number 10701284): Test Reagents QuantiFERON, Lot # 137287, Quantity 21 Mumps, Lot # 163044A, Quantity 2 Measles, Lot # 159051, Quantity 2 Varicella Zoster, Lot # 392005, Quantity 2 Rubella, Lot # 306023, Quantity 2 Hepatitis B Core, Lot # 265014, Quantity 3 Hepatitis B Surface Antigen, Lot # 277046, Quantity 2 Hepatitis B Antibody, Lot # 271025, Quantity 3 Hepatitis C Antibody, Lot # 279036, Quantity 3 Quality Control QuantiFERON, Lot # 137309A, Quantity 4 Mumps, Lot # 164047A,</p>

Quantity 2 Measles, Lot # 160036, Quantity 2 Varicella Zoster, Lot # 393004, Quantity 1 Rubella, Lot # 009043A, Quantity 2 Hepatitis B Core, Lot # 266010, Quantity 3 Hepatitis B Surface Antigen, Lot # 278032, Quantity 3 Hepatitis B Antibody, Lot # 272013, Quantity 3 Hepatitis C Antibody, Lot # 280033, Quantity 2 a. Each test reagent and quality control kit indicated on the box container, a storage temperature requirement of 2 - 8C. 2. A review of the manufacturer's package inserts for the test reagents and quality control material stated a storage temperature requirement of 2 - 8C. 3. A review of the Serology temperature recording chart revealed a temperature range of 1 - 5C +/- 1C for the VWR refrigerator (serial number 10701284). 4. A review of Serology temperature recording charts from 04/01/2023 to 04/30/2025, revealed 2 out of 760 days the refrigerator temperature was recorded as follows: Date Temperature 10/18/2023 1.6 C 04/02/2024 1.0 C 5. An interview on 04/30/2025 at 9:15 AM with the Serology General Supervisor confirmed that the laboratory failed to define specified temperature requirements for the storage of Diasorin test reagents and quality control material in the VWR refrigerator, serial number 1070284. 6. An interview on 04/30/2025 at 11:55 AM with the Quality Assurance Coordinator confirmed that 2 out of 760 days, the recorded temperature for the VWR refrigerator (serial number 10701284) was outside the manufacturer's specified storage temperature range of 2 - 8C.

**D5805**

**TEST REPORT**  
CFR(s): 493.1291(c)

(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.

This STANDARD is not met as evidenced by:

Based on review of the laboratory's policy, review of patient test reports, and interview with the Laboratory Director, the laboratory failed to include test results on the patient test reports with multiplex SARS COV-2 (FLU SC2) Multiplex Assay for 2 of 2 months reviewed (February and March) 2025: 1. In review of the laboratory's policy CMS.491 PHL CDC Influenza SARS-COV-2 (Flu SC2) Multiplex Assay shows a table on pg 16. The table indicates the following: INFA + report positive for Influenza A inf B + report positive for Influeza B SC2 + report positive for Covid -19 INFA - INFB - SC2 - report negative. 2. In review of the following patient test reports, the laboratory did not put the final results (positive or negative) on the patient test reports for Influenza virus A, Influenza Virus B, and SARS-COV-2. a. patient 30361 report 2/10/2025. b. patient 102809 report 3/10/2025. 3. In interview with the laboratory director on 5/1/2025 at 1222, confirmed the results weren't on the test reports only the interpretation.