Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	53D0662169	11/17/2022
Name of Provider or Supplier	**Street Address, City, State**	
Wyoming Public Health Laboratory	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.

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on a direct observation and an interview with microbiology General Supervisor, the laboratory failed to ensure that the REMEL Bactidrop Oxidase reagent was not used past the expiration date. The laboratory performed 34 Oxidase tests with the expired reagent from 08/13/2022 to 11/17/2022. Findings include: 1. A direct observation of the microbiology BSL2 hood revealed one (1) open box of single use vials of REMEL Bactidrop Oxidase reagent, lot number 202384, with an expiration date of 08/13/2022, was being used for bacterial culture identification on patient culture specimens. 2. An interview with the General Supervisor on 11/17/2022, at approximately 3:10 PM, confirmed the REMEL Bactidrop Oxidase reagent was expired and was used for patient testing.
D5775	COMPARISON OF TEST RESULTS CFR(s): 493.1281(a)(c) (a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. (c) The laboratory must document all test result comparison activities. This STANDARD is not met as evidenced by:

	Based on a record review and an interview with the Laboratory Director, the laboratory failed to have a system in place to document the comparison of six (6) Applied Biosystems 7500 Fast Dx instruments used for the CDC Multiplex Assay for Influenza A, B, and SARS-CoV-2 testing at least twice a year since September of 2020. The laboratory performed approximately 50,000 tests per year. Findings include: 1. A review of the laboratory's quality assurance records revealed that the laboratory failed to have a system in place to evaluate the CDC Multiplex Assay for Influenza A, B, and SARS-CoV-2 patient test results using 6 Applied Biosystems 7500 Fast Dx instruments. 2. An interview with the Laboratory Director on 11/17 /2022, at approximately 2:30 PM, confirmed the laboratory failed to have a system that twice a year evaluates the relationship between 6 Applied Biosystems 7500 Fast Dx instruments used for patient testing.
D5787	TEST RECORDS CFR(s): 493.1283(a) The laboratory must maintain an information or record system that includes the following: (a)(1) The positive identification of the specimen. (a)(2) The date and time of specimen receipt into the laboratory. (a)(3) The condition and disposition of specimens that do not meet the laboratory's criteria for specimen acceptability. (a)(4) The records and dates of all specimen testing, including the identity of the personnel who performed the test(s). This STANDARD is not met as evidenced by: Based on a review of the laboratory's bacteriology culture worksheets and an interview with the microbiology General Supervisor, the laboratory failed to document or have a system in place to ensure the bacteriology culture worksheets included the dates and testing personnel for each step of bacterial organism identification process, from media inoculation through organism isolation and identification since the last survey performed on 11/3/2020. The laboratory performed approximately 1500 bacteriology culture tests per year. Findings include: 1. Review of the laboratory's bacteriology culture worksheets revealed the laboratory failed to document the dates and the identity of the testing personnel who performed each step in the organism isolation and identification process since the last survey performed on 11/3/2020. 2. An interview with the microbiology General Supervisor on 11/17/2022, at 3:30 PM, confirmed the laboratory's culture worksheets did not include the identity of the testing personnel and the dates of each testing step.