Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 53D0662169	**(X3) Date Survey Completed** 11/03/2020
Name of Provider or Supplier Wyoming Public Health Laboratory	**Street Address, City, State** 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**
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 observation of the extraction room for PCR COVID-19 testing, lack of temperature and humidity documentation, Qiagen manufacturer's insert, and interview with the laboratory director (LD), the laboratory failed to monitor and document the temperature and humidity of the extraction room used for PCR COVID-19 testing. Findings: 1. Observation of the extraction room for the PCR COVID-19 testing, revealed the laboratory failed to monitor and document the temperature and humidity since March 4, 2020. 2. Review of the Qiagen manufacturer's product insert revealed that operating conditions must be in a temperature range of 18 to 28 degrees Celsius and a relative humidity of 15 to 75 percent (noncondensing). 3. Interview with the LD on November 3, 2020 at 3:00 PM confirmed the laboratory failed to monitor and document the room temperature and humidity in the extraction room for PCR COVID-19 testing.