Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	53D0519764	09/09/2020
Name of Provider or Supplier	**Street Address, City, State**	
Wyomed Laboratory Inc	204 Mccollum St, Ste 105, Laramie, 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
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods. This STANDARD is not met as evidenced by: Based on proficiency testing records review, lack of documentation, and interview with staff, laboratory testing personnel failed to attest to the routine integration of proficiency samples into the patient workload using the laboratory's routine Complete Blood Count (CBC) methods for 1 of 6 American Proficiency Institute (API) testing events reviewed. Findings include: 1. Proficiency testing records review failed to include the signed attestation statement from the 3rd API Hematology (CBC) event of 2018. 2. In an interview with staff on 09/09/2020 at approximately 1:55 P.M., staff confirmed they lacked the attestation statement from the 3rd API Hematology (CBC) event of 2018.
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 temperature records review, Complete Blood Count (CBC) control reagent storage temperature requirement review, lack of documentation, and interview with staff, the laboratory failed to ensure they monitored refrigerator storage temperatures each day of testing for 1 of 13 months of testing reviewed. Findings include: 1. Temperature records review for March 2019 failed to include documentation the laboratory monitored the storage refrigerator for 14 of 21 test days in March of 2019. The laboratory failed to record temperatures between March 1st and March 12th; March 15th, March 18, March 21st, March 24th and between March 24th and March 28th. 2. Manufacturer's instructions review as printed on the CBC control reagents included the storage temperature of 2 to 8 degrees C. 3. In an interview conducted on 09/09/2020 at approximately 2:00 P.M., staff confirmed the temperatures were not monitored each day of testing in March of 2019.