Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	53D0519699	02/19/2025
Name of Provider or Supplier	**Street Address, City, State**	
University-Wyoming Family Practice	820 East 17th Street, 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
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. In addition, retain the following: This STANDARD is not met as evidenced by: Based on review of laboratory records, lack of documentation and staff interview, the laboratory failed to retain documentation of quality control and preventative maintenance for 2 of 2 years reviewed (2023, 2024). The laboratory performed urine dipsticks, HBA1C, viral respiratory panels, and glucose testing. The findings were: 1. Review of the laboratory's records showed quality control was documented on a log sheet for the Cepheid and Afinion analyzers. Both analyzers had quality control performed on 1/29/25. Further review of the laboratory's records showed no documentation of the quality control results for 2023 and 2024. Further review showed no evidence the manufacturer's recommended maintenance tasks had been performed. 2. Interview with the clinic manager and the nursing supervisor on 2/19/25 at 9:25 AM revealed the laboratory used a glucometer for glucose testing, performed urine dipsticks, HbA1c testing on the Afinion analyzer, and used the Cepheid GeneXpert Xpress analyzer for performing viral respiratory panels. In addition, the laboratory underwent a process change in January of 2025 after employment was terminated with the staff member responsible for the laboratory testing. The process change included documenting the date, lot numbers, and results of quality control testing on the Cepheid and Afinion analyzers. The nursing supervisor revealed glucose and urine dipstick quality control was a work in progress and had not been performed in 2025. Documentation of the manufacturer's recommended maintenance tasks and quality control data for 2023 and 2024 could not be located.

D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) (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. This STANDARD is not met as evidenced by: Based on observation, lack of documentation, review of manufacturer's instructions, and staff interview, the laboratory failed to monitor room temperature and humidity in the testing areas. The laboratory performed approximately 160 HbA1c patient tests on the Afinion analyzer and 50 respiratory viral panels on the Cepheid GeneXpert Xpress analyzer since 7/30/24. The findings were: 1. Observation on 2/19/25 at 9:25 AM showed laboratory testing took place in two separate areas. The Afinion analyzer was in a small, windowless room with other electrical equipment. A box of test cartridges was located on the counter dated 1/25/25. The Cepheid analyzer was in a separate room and set up next to a window. Cold air could be felt emanating from the window. Review of the laboratory's documentation showed no evidence the temperature and humidity of the testing areas were monitored. 2. Review of the Afinion manufacturer's instructions showed the test cartridges could be stored in unopened foil pouches at 15 to 25 degrees Celsius (59 to 77 degrees Fahrenheit) for 90 days. Further review showed testing should be performed between 15 and 32 degrees Celsius (59 to 89 degrees Fahrenheit) to obtain optimal results. 3. Review of the Cepheid GeneXpert Xpress manufacturer's instructions showed the environmental conditions for testing should be between 15 and 30 degrees Celsius and a humidity level between 20% and 80% should be maintained. 4. Interview with the nursing supervisor on 2/19/25 at 9:55 AM revealed environmental monitoring of the testing areas was not completed.
D5431	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(2) (a)(2) Function checks as defined by the manufacturer and with at least the frequency specified by the manufacturer. Function checks must be within the manufacturers established limits before patient testing is conducted. (b) Equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer. The laboratory must do the following: This STANDARD is not met as evidenced by: Based on lack of documentation, staff interview, and review of the Cepheid GeneXpert Xpress and Afinion HbA1c operator's manuals, the laboratory failed to follow the manufacturer's instructions to perform cleaning and preventative maintenance procedures as recommended for 2 of 2 years reviewed (2023, 2024). The findings were: 1. Review of the laboratory's documentation showed no evidence the required preventative maintenance was performed on the Cepheid and Afinion analyzers. 2. Review of the Afinion Installation and Training Guide showed "The

	cartridge chamber should be cleaned immediately if materials or liquids are spilled in the cartridge chamber. For regular maintenance (removal of dust particles etc.), the cartridge chamber should be cleaned every 30 days." 3. Review of the Cepheid GeneXpert Xpress operator's manual showed the manufacturer recommended daily, weekly, monthly, quarterly, annual, and as necessary maintenance tasks to ensure the performance of the system and to help avoid malfunctions and errors. 4. Interview with the nursing supervisor on 2/19/25 at 9:25 AM revealed the laboratory underwent a process change in January of 2025 after employment was terminated with the staff member responsible for the laboratory testing. Documentation of the manufacturer's recommended maintenance tasks could not be located.