

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 53D2271228	(X3) Date Survey Completed 06/15/2023
Name of Provider or Supplier Hoskinson Health & Wellness Clinic	Street Address, City, State 469 Wy-50, Gillette, 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	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's environmental records, review of manufacturer's instructions, and staff interview, the laboratory failed to monitor humidity in the testing area. The laboratory estimated it would perform approximately 10,700 patient tests annually. The findings were: 1. Review of the laboratory's daily environmental log sheet showed the relative humidity in the testing area of the facility was not monitored. 2. Review of the Sysmex XN 550 manufacturer's instructions showed the relative humidity of the operating environment should be between 20 and 85 percent. 3. Interview with the technical consultant on 6/15/23 at 3:33 PM confirmed the laboratory did not monitor the relative humidity of the testing area.</p>