

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 44D1039229	(X3) Date Survey Completed 05/23/2022
Name of Provider or Supplier Wellmont Health System	Street Address, City, State 1519 Main Street, Sneedville, TN	
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:</p> <p>===== Based on review of the HCH Laboratory Services Temperature (and Humidity) Chart and interview with the lead laboratory technologist, it was determined that the laboratory failed to ensure the humidity was maintained at 30-80% for five of 23 months reviewed in 2020, 2021, and 2022. The Findings include: 1. Review of the Temperature (and Humidity) Chart revealed the humidity was out of the defined range (30-80%) in the year 2021 for the following months: -November (3 of 30 days) in the year 2022 for the following months: -January (3 of 31 days) -February (3 of 28 days) -March (2 of 31 days) -April (2 of 30 days) 2. An interview with the lead laboratory technologist on May 23, 2022 at approximately 12:15 pm confirmed the laboratory failed to ensure the humidity was within acceptable range in 2021 and 2022.</p> <p>=====</p>