

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 07D2310544	(X3) Date Survey Completed 07/01/2025
Name of Provider or Supplier Prime Healthcare	Street Address, City, State 30 Jordan Ln, Wethersfield, CT	
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>(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.</p> <p>This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed for follow the manufacturer specified requirements to ensure acceptable humidity is obtained in the subspeciality of histopathology. Findings include: 1. Record review on 7/1/2025 of the 'Tissue-Tek VIP 5 Vacuum Infiltration Processor' operating manual revealed that "Relative Humidity - 30% to 85% RH". 2. Record review on 7/1/2025 of the laboratory's 'Daily Temperature and Humidity Check' log revealed acceptable ranges for humidity is: 20-80%. 3. Record review on 7/1/2025 of the laboratory's 'Daily Temperature and Humidity Check' log revealed humidity is less than 30% for 65/99 days from January 2025 - May 2025. 4. Staff interview on 7/1/2025 at 10:55 AM with the laboratory director confirmed the above findings. 5. The laboratory performs 9,000 tests annually in the subspeciality of histopathology.</p>