

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 44D2007076	(X3) Date Survey Completed 06/10/2024
Name of Provider or Supplier Spring Hill Dermatology, Plc	Street Address, City, State 100 Blythewood Dr Suite A, Columbia, 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: Based on observation of the laboratory, review of the manufacturer's instruction manual, environmental records, annual test volumes reported on Form CMS-116, and staff interview, the laboratory failed to monitor ambient room temperature and humidity where patient tissue processing occurred in 2022, 2023, and 2024. 1. Observation of the laboratory on 06/10/24 at 08:15 a.m. revealed an Intelsint RVG/1 Histology Vacuum Tissue Processor (SN1344/172) in use for processing patient dermatopathology tissue samples. 2. A review of the Intelsint RVG/1 - Histology Vacuum Tissue Processor Installation, Use and Maintenance manual revealed a running ambient temperature requirement of 10 / 35 C and a relative humidity requirement of Max 80% (not condensing). 3. A review of the laboratory environmental records revealed no room temperature or humidity records were available for the area where the laboratory processed tissues using the Intelsint RVG/1 Tissue Processor in 2022, 2023, or 2024. 4. A review of the Form CMS-116 annual test volume estimates revealed approximately 18,500 tissue sample results reported in 2022, 2023, and 2024 (06/01/2022-06/10/2024). 5. An interview on 06/10/2024 at 11: 45 a.m. with the laboratory director and the laboratory manager confirmed the laboratory did not monitor laboratory room temperature or humidity in 2022, 2023, or 2024.</p>