

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 39D2332313	(X3) Date Survey Completed 03/19/2026
Name of Provider or Supplier St Luke's Dermatology Walbert Ave	Street Address, City, State 3151 Walbert Ave, Suite 301, Allentown, PA	
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	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 lack of documentation and interview with the Mohs Technician (MT), the laboratory failed to monitor and document room temperature and humidity to ensure operating conditions were met for 1 of 1 Labomed microscope used to perform Potassium Hydroxide Preparation (KOH) and wet mount examinations from 12/01/2025 to 03/19/2026. Findings include: 1. The manufacturers operating environment specifications stated, " Labomed microscope: 5-40 degrees Celsius (ambient temperature); maximum 80 % relative humidity." 2. On the day of the survey, 03/19/2026 at 10:00 am, the laboratory failed to provide documentation for the monitoring of room temperature and humidity to ensure operating conditions were met for the following instruments used to perform KOH and wet mount examinations from 12/01/2025 to 03/19/2026: - 1 of 1 Labomed microscope 3. The laboratory performed 50 KOH and wet mount examinations in 2026 (CMS 116, estimated annual volume, dated 03/09/2026). 4. The MT confirmed the findings above on 3/19/2026 at 10:45 am.