

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 39D0887030	(X3) Date Survey Completed 04/29/2025
Name of Provider or Supplier Yardley Dermatology Associates, Pc	Street Address, City, State 803 Floral Vale Boulevard, Yardley, 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	<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 review of the laboratory's temperature records, and interview with the Histology Technician (HT), the laboratory failed to monitor and document temperatures to ensure operating conditions were met for reliable test system operation and test result reporting for 2 of 2 cryostats (Avantik QS11 and QS12) used to perform MOHS microscopic slide examinations from 06/07/2023 to date of survey. Findings Include: 1. On the day of the survey, 04/29/2025 at 09:15 am, review of the laboratory's temperature logs revealed the laboratory failed to monitor and document 2 of 2 cryostat temperatures (manufacturers acceptable range: -21 to -26 degrees Celsius) to ensure reliable test system operation and test result reporting for 06/07/2023 to 04/29/2025 when MOHS microscopic slide examinations were performed. 2. The laboratory performed 9982 histopathology examinations in 2024 (CMS 116, estimated annual volume). 3. The HT confirmed the findings above on 04/2/2025 at 09:25 am.</p>