Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	39D0185974	06/24/2026
Name of Provider or Supplier	**Street Address, City, State**	
Dermatology Associates Of Lebanon	845 Norman Drive, Lebanon, 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 Laboratory Director (LD), the laboratory failed to monitor and document room temperature (RT) and room humidity (RH) to ensure operating conditions were met for 1 of 1 Olympus CH microscope used to perform histopathology microscopic slide examinations from 12/18/2024 to 06/24/2026. Findings include: 1. On the day of the survey, 06/24/2026 at 09:45 am, the laboratory failed to provide documentation for the monitoring of RH to ensure operating conditions were met for the following equipment used to perform histopathology microscopic examinations from 12/18/2024 to 06/24/2026: - 1 of 1 Olympus CH microscope: S/N 816285 (manufacturer's operating environment specifications: 5-40 degrees Celsius, 30-80 % relative humidity) 2. During interview on 06/24/2026 at 09:50 am, the LD stated "room temperature was taken using the thermostat on the wall." The LD could not provide maintenance/function checks for the wall thermostat used to monitor room temperature from 12/18/2024 to 06/24/2026. 3. The laboratory performed 3,690 histopathology microscopic slide examinations in 2025 (CMS 116, estimated annual volume, dated 04/15/2026). 4. The LD confirmed the above findings on 06/24/2026 at 10:00 am.

D6093	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) (e)(5) Ensure that the quality control and quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur; This STANDARD is not met as evidenced by: Based on review of laboratory procedure, lack of documentation and interview with the Laboratory Director (LD), the LD failed to follow and maintain the laboratory's established Quality Assessment (QA) program for 2 of 2 years from 12/19/2023 to 06/24/2026. Findings included: 1. The laboratory's Quality Assurance Manual stated, "Quality Assessment will be performed annually." 2. On day of the survey, 06/24/2026 at 09:30 am, the laboratory failed to provide documentation of the laboratory's annual QA performed for 2 of 2 years from 12/19/2023 to 06/24/2026. 3. The laboratory performed 3,690 histopathology microscopic slide examinations in 2025 (CMS 116, estimated annual volume, dated 04/15/2026). 4. The LD confirmed the finding above on 06/24/2026 at 10:00 am.