Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	39D0673421	10/09/2025
Name of Provider or Supplier	**Street Address, City, State**	
Dermatology Physicians Inc	2106 Harrisburg Pike Suite 314, Lancaster, 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
D0000	A routine recertification survey was conducted by the Pennsylvania State Agency at Dermatology Physicians Inc on 10/09/2025. The laboratory was found out of compliance with the following condition: 493.1250 Condition: Analytic systems.
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on observation of the laboratory, record review, and interview with the Laboratory Supervisor (LS), the laboratory failed to meet applicable analytic systems requirements in 493.1251 through 493.1283 from 11/01/2024 to date of survey. Refer to D5417.
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 Lab Supervisor (LS), the laboratory failed to monitor and document room temperature and humidity to ensure operating conditions were met for 1 of 1 microscopes used to perform Potassium Hydroxide (KOH) microscopic slide examinations from 9/15/2023 to 10/09/2025. Findings Include: 1. On the day of survey, 10/09/2025 at 09:40 am, the laboratory failed to provide documentation for monitoring room temperature (laboratory's acceptable range 65 - 72 degrees Fahrenheit) and relative humidity (laboratory's acceptable range 0 - 60%) to ensure operating conditions were met for the following instrumentation used to perform KOH microscopic slide examinations from 9/15/2023 to 10/09/2025: - 1 of 1 Omega microscope (s/n 0820592) 2. The laboratory performed 5 KOH microscopic slide examinations in 2024 (CSM 116, estimated annual volume, dated 10/09/2025). 3. The LS confirmed the findings above on 10/09/2025 at 10:27 am.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) (d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on observation of the laboratory, record review, and interview with the Laboratory Supervisor (LS), the laboratory failed to ensure that 1 of 1 reagent used to perform Potassium Hydroxide (KOH) microscopic slide examinations was not used beyond its expiration date from 11/01/2024 to date of survey. Findings include: 1. On the day of the survey 10/09/2025 at 09:37 am, observation during the laboratory tour revealed the following 1 of 1 expired reagents currently being used to perform KOH microscopic slide examinations from 11/01/2024 to 10/09/2025: - 1 opened bottle of Delasco 20% KOH with DMSO (Lot #K21AB, expired 10/31/2024). 2. Review of the laboratory's "Quality Control of KOH Preparation" log revealed that 2 KOH Prep microscopic slide examinations were performed from 11/01/2024 to 10/09/2025. 3. The LS confirmed the findings above on 10/09/2025 at 10:27 am. **Repeat deficiency**
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) (a)(1) Maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on review of the laboratory's Quality Control Policy for Laboratory Equipment, lack of documentation, and interview with the Laboratory Supervisor (LS), the laboratory failed to perform the preventative maintenance/function checks for 1 of 1 microscopes used for Potassium Hydroxide (KOH) microscopic slide examinations from 9/15/2023 to the day of survey. Findings Include: 1. The laboratory's "Quality

	Control Policy for Laboratory Equipment, Microscopes" states, "Preventative maintenance will be done annually by Dolby Jamison [Biomed service provider]." 2. On the day of survey, 10/09/2025 at 9:40 am, the laboratory failed to provide maintenance/function check records of the annual preventative maintenance performed for the following 1 of 1 microscopes used from 9/15/2023 to 10/09/2025: - Omega microscope (s/n 0820592) 3. The laboratory performed 5 KOH microscopic slide examinations in 2024 (CSM 116, estimated annual volume, dated 10/09/2025). 4. The LS confirmed the findings above on 10/09/2025 at 10:27 am.