

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 39D2116761	(X3) Date Survey Completed 05/12/2026
Name of Provider or Supplier Commonwealth Dermatology	Street Address, City, State 3055 Washington Road Suite 203, McMurray, 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 for Commonwealth Dermatology on 05/12/2026. The laboratory was found out of compliance with the following conditions: 493.1230 Condition: General laboratory systems. 493.1250 Condition: Analytic systems.
D5200	GENERAL LABORATORY SYSTEMS CFR(s): 493.1230 Each laboratory that performs nonwaived testing must meet the applicable general laboratory systems requirements in 493.1231 through 493.1236, 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 general laboratory systems and correct identified problems specified in 493.1239 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on review of the laboratory's peer review records, and interview with the Office Manager (OM), the laboratory failed to ensure that general laboratory systems requirements were met under 493.1236 for the verification of accuracy for parasitology microscopic examinations (scabies) performed for 12 of 12 months in 2025. Refer to 5217
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by:

	Based on record review, lack of documentation, and interview with the office manager (OM), the laboratory failed to ensure that the verification of accuracy for parasitology microscopic examinations (scabies) was performed at least twice annually, as required for tests not included in subpart I for 12 of 12 months in 2025. Findings include: 1. On the day of the survey, 05/12/2026 at 10:00 am, the laboratory could not provide documentation that the verification of accuracy for scabies microscopic examinations was performed twice annually for 12 of 12 months in 2025. 2. Review of the laboratory's patient test logs revealed the laboratory performed 4 scabies examinations in 2025. 3. The OM confirmed the findings above on 05/12/2026 at 11:15 am. ***Repeat deficiency***
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 review of temperature and humidity logs, lack of documentation, and interview with the Office Manager (OM), the laboratory failed to monitor and document room temperature and humidity as required under 493.1252 to ensure reliable test system operation and test result reporting for instrumentation used to perform Potassium Hydroxide (KOH), and dermatopathology (MOHS) microscopic examinations for 25 of 291 days from 07/18/2024 to 05/12/2026. Refer to D5413
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 review of the laboratory's room temperature and humidity records, lack of documentation, and interview with the Office Manager (OM), the laboratory failed to monitor and document room temperature (RT) and relative humidity (RH) for 25 of 291 days to ensure operating conditions were met for reliable test system operation of the Leica DM1000 microscope and Avantik QS12 cryostat and test result reporting of Potassium Hydroxide (KOH) and dermatopathology (MOHS) microscopic slide examinations performed from 07/30/2024 to 05/12/2026. Findings Include: 1. On the day of the survey, 05/12/2026 at 10:15 am, review of the laboratory's RT and RH control logs revealed the laboratory failed to monitor and document RT and RH for

the following 25 of 291 days when KOH and MOHS microscopic slide examinations were performed from 07/30/2024 to 05/12/2026: Relative humidity (laboratory's acceptable range: less than 60% RH): - 07/30/2024 - 07/31/2024 - 08/01/2024 - 08/15/2024 - 08/19/2024 - 08/20/2024 - 08/21/2024 - 08/26/2024 - 08/27/2024 - 08/28/2024 - 08/29/2024 - 09/11/2024 - 10/02/2024 - 10/03/2024 - 10/31/2024 - 11/19/2024 - 11/20/2024 - 08/29/2025 - 09/04/2025 - 09/11/2025 - 01/05/2026 - 01/12/2026 - 01/19/2026 - 02/02/2026 - 03/12/2026 Room temperature (laboratory's acceptable range: 68 to 76 degrees Fahrenheit): - 09/11/2024 - 10/02/2024 - 10/03/2024 - 11/19/2024 - 11/20/2024 - 08/29/2025 - 09/11/2025 - 01/05/2026 - 01/12/2026 - 01/19/2026 - 02/02/2026 - 03/12/2026 2. Review of the laboratory's test logs revealed the laboratory performed 3 KOH and 151 MOHS microscopic examinations from 07/30/2024 to 05/12/2026. 3. The OM confirmed the findings above on 05/12/2026 at 11:20 am.

Repeat deficiency