Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 39D2069206	**(X3) Date Survey Completed** 09/11/2025
Name of Provider or Supplier Lackawanna Valley Dermatology Assoc Ltd	**Street Address, City, State** 440 Pierce Street, Kingston, 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 Clinical Coordinator (CC), the laboratory failed to monitor and document room humidity to ensure operating conditions were met for 1 of 1 Leica DM1000 microscope used to perform mycology and parasitology slide examinations and 2 of 2 Avantik cryostat (QS11/ QS12) for histopathology (Mohs) microscopic slide from 02/15/2025 to the day of survey. Findings include: 1. The manufacturer's operating environment specifications for Lecia DM1000 microscope are 5-35 degrees Celsius (ambient temperature) and maximum 80% relative humidity and for the Advantik cryostat are 5-35 degrees Celsius (ambient temperature) and maximum 60% relative humidity. 2. On the day of the survey, 09/11/2025, the laboratory failed to provide documentation of the monitoring of room humidity to ensure operating conditions were met to perform microbiology and histopathology (Mohs) microscopic examinations from 02/15/2024 to 09/11/2025 for the following instruments: - 1 of 1 Lecia DM1000 microscope - 2 of 2 Avantik cryostat (QS11/QS12) 3. The laboratory performed 266 microbiology and 1075 histopathology slide examinations in 2024 (CMS 116, estimated annual volume, dated 09/10/2025). 4. The CC confirmed the above findings on 09/11/2025 at 09: 30am.

D5805	TEST REPORT CFR(s): 493.1291(c) (c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: Based on review of patient test reports (Preoperative notes and Mohs Maps) and interview with the Clinical Coordinator (CC) and Histotech (HT), the laboratory failed to include the address of the location where MOHS microscopic slide examinations (histopathology) were performed on 2 of 2 patient test reports reviewed from 02/15 /2024 to the date of the survey. Findings include: 1. On 09/11/2025 at 09:45 am, review of 2 of 2 patient test reports (Preoperative notes and Mohs maps) revealed the laboratory failed to ensure the addition of the address of the laboratory where MOHS microscopic slides were examined from 02/15/2024 until 09/11/2025. 2. The laboratory performed 1075 microscopic slide examinations (histopathology) in 2024 (CMS 116, estimated annual volume, dated 09/10/2025). 3. The CC and HT confirmed the above findings on 09/11/2025 at 09:45 am.