

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 39D0940659	(X3) Date Survey Completed 04/07/2025
Name of Provider or Supplier Lackawanna Valley Dermatology Assoc	Street Address, City, State 327 North Washington Avenue Suite 200, Scranton, 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 lack of documentation and interview with the Clinical Coordinator, the laboratory failed to monitor and document room temperature and humidity to ensure operating conditions were met for 1 of 1 McKesson Lumeon series microscope used to perform mycology and parasitology microscopic slide examinations from 11/13 /2023 to the day of survey. Findings include: 1. The manufacturer's operating environment specifications for the McKesson Lumeon series microscope are 5-35 degrees Celsius (ambient temperature) and maximum 80% relative humidity. 2. On the day of the survey, 04/07/2025, the laboratory failed to provide documentation of the monitoring of room temperature and humidity to ensure operating conditions were met for the 1 of 1 McKesson Lumeon series microscope (s/n 20200090) used to perform DTM fungal cultures (dermatophyte screening), potassium hydroxide (KOH) and ectoparasite (scabies) microscopic examinations from 11/13/2023 to 04/07/2025. 3. The laboratory performed 71 dermatophyte screenings, 234 KOH and 79 scabies microscopic examinations from 11/13/2023 to 04/07/2025. 4. The Clinical Coordinator confirmed the above findings on 04/07/2025 at 1:26 pm.</p>