

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 39D0908941	(X3) Date Survey Completed 06/12/2025
Name of Provider or Supplier Joseph J Zaladonis Jr Md Lab	Street Address, City, State 1665 Valley Center Parkway, Suite 120, Bethlehem, 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 review of laboratory records, lack of documentation, and interview with the Mohs Technician (MT), the laboratory failed to monitor and document room temperature and humidity to ensure operating conditions were met for 1 of 1 Labomed CXL Microscope used to perform Potassium Hydroxide (KOH)/Scabies slide examinations fom 08/01/2023 to the date of survey. Findings include: 1. The operating environment listed in the instruction manual for the Labomed CXL biological microscope states: "microscope should be kept at temperatures between 5C-40C/41F-104F, with a maximum humidity of 80%." 2. On the date of the survey, 06/12/2025 at 09:30 am, the laboratory failed to provide documentation for monitoring room temperatures and humidity to ensure operating conditions were met for 1 of 1 Labomed CXL microscope used to perform KOH/Scabies slide examinations from 08/01/2023 to 06/12/2025. 3. The laboratory performed 100 (CMS-116 estimated annual volume) KOH/Scabies slide examinations in 2024. 4. The MT confirmed the findings above on 06/12/2025 at 09:30 am.</p>