

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 39D2285982	(X3) Date Survey Completed 08/14/2025
Name of Provider or Supplier Geisinger Oral Pathology	Street Address, City, State 675 Baltimore Drive, Wilkes Barre, 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 Laboratory Director (LD), the laboratory failed to monitor and document room temperature and humidity to ensure operating conditions were met for 1 of 1 Nikon Eclipse Ci-L Plus Microscope used to perform histopathology slide examinations from 12/20/2023 to the date of survey. Findings include: 1. The operating conditions listed in the instruction manual for the Nikon Eclipse Ci-L Plus microscope states: "temperature: 0 C to 40C, maximum relative humidity: 60%." 2. On the date of the survey, 08/14/2025 at 1:25 pm, the laboratory failed to provide documentation for monitoring room temperatures and humidity to ensure operating conditions were met for the 1 of 1 Nikon Eclipse Ci - L Plus microscope (s/n 71173) used to perform histopathology slide examinations from 12/20/2023 to 08/14/2025. 3. The laboratory performed 17,979 histopathology slide examinations from 12/20/2023 to 08/14/2025. 4. The LD confirmed the findings above on 08/14/2025 at 1:36 pm.</p>