

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 39D2327991	(X3) Date Survey Completed 01/13/2026
Name of Provider or Supplier Udhs Oral Pathology Biopsy Svc	Street Address, City, State 3501 Terrace St, Pittsburgh, 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 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 for 5 of 5 months to ensure reliable test system operation and test result reporting for instrumentation used to perform oral pathology microscopic slide examinations from 08/05/2025 to 1/13/2026. Findings include: 1. On the date of the initial survey, 01/13/2026 at 1:04 pm, the laboratory could not provide documentation for monitoring room temperature and humidity (manufacturer's acceptable range 5 to 40 degrees Celsius, max 80% RH) to ensure operating conditions were met for the following instrumentation used to perform oral pathology microscopic slide examinations for 5 of 5 months from 08/05/2025 to 01/13/2026: - 1 of 1 Olympus BX 53 microscope (s/n 2A67029) - 3 of 3 Olympus BX 46 microscopes (s/n OJ63768, OM47527, 9L1705) 2. The laboratory performed 3100 oral pathology microscopic slide examinations in 2025 (CMS 116, estimated annual test volume, dated 01/13/2026). 3. The LD confirmed the findings above on 01/13/2026 at 1:19 pm.