

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 39D1084575	(X3) Date Survey Completed 04/15/2026
Name of Provider or Supplier Keystone Derm Ctr For Skin Surg Llc	Street Address, City, State 2525 9th Avenue Suite 2a, Altoona, 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 Laboratory Supervisor (LS), the laboratory failed to monitor and document room humidity to ensure operating conditions were met for 1 of 1 Amscope microscope, 1 of 1 Olympus BX40 microscope, and 2 of 2 Microm HM520 cryostats used to perform histopathology (Mohs) and microbiology microscopic slide examinations from 04/22/2024 to 04/15/2026. Findings include: 1. On the day of the survey, 04/15/2026, the laboratory failed to provide documentation for the monitoring of room humidity to ensure operating conditions were met for the following instruments used to perform histopathology (Mohs) and microbiology microscopic examinations (scabies, potassium hydroxide (KOH), and Tzanck smears) from 04/22/2024 to 04/15/2026: - 1 of 1 Amscope microscope: manufacturer's operating condition relative humidity range 30-80% - 1 of 1 Olympus BX40 microscope: manufacturer's operating condition relative humidity range 30-85% - 2 of 2 Microm HM520 cryostat: manufacturer's operating condition relative humidity range 0- 60% 2. The laboratory performed 2,319 histopathology (Mohs) slide examinations and 53 microbiology (scabies, KOH, Tzanck smears) slide examinations in 2025 (CMS 116, estimated annual volume, dated 04/15/2026). 3. The LS confirmed the above findings on 04/15/2026 at 10:30 am.</p>