

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 34D2279606	(X3) Date Survey Completed 07/23/2026
Name of Provider or Supplier Tlk Dermatology Pllc	Street Address, City, State 530 New Waverly Place, Suite 101, Cary, NC	
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 manufacturer's instruction and user manuals, review of 2024, 2025, and 2026 laboratory temperature and humidity logs, surveyor observation, and interview with Testing Personnel (TP #2) on July 23, 2026, the laboratory failed to define acceptable humidity ranges consistent with manufacturer requirements and failed to monitor and document humidity for approximately 27 months of patient testing between 05/09/2024 to 07/23/2026. Findings: Review of "The Avantik QS12 Cryostat" instruction manual revealed on page 14, "Environmental Specifications... Relative Humidity...Max. 60% RH up to 35C..." Review of the "Leica Microsystems Leica DM750" user manual revealed on page 15, "Environment...Humidity during use and storage 20-90%..." Review of 2024, 2025, and 2026 "Room Temperature / Humidity" laboratory logs revealed: 1. Laboratory log title included "...Humidity" and a humidity range "...60% >..." 2. Humidity was not monitored and documented for approximately 27 months of patient testing: 05/09/2024 - 12/31/2024 (approximately 8 of 12 months) 01/01/2025 - 12/31/2025 (12 of 12 months) 01/01/2026 - 07/23/2026 (approximately 7 of 12 months) During a tour of the laboratory on 07/23/2026 at approximately 1:00 p.m., the surveyor observed a digital thermometer for reading and recording temperature and the absence a hygrometer for reading and recording

relative humidity. During interview on 07/23/2026 at approximately 1:30 p.m., TP #2 confirmed the laboratory does not have a hygrometer for recording humidity and readings for 2024, 2025, and 2026 were missed. TP #2 said she took over as lab lead in April 2026 and was not aware humidity needed to be recorded because the previous lab lead never recorded humidity.