

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D2176553	(X3) Date Survey Completed 05/30/2025
Name of Provider or Supplier Nikko Dermatology	Street Address, City, State 27150 Us-290 Suite 100, Cypress, TX	
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
D0000	An announced survey of the laboratory was conducted on 05/30/2025. The laboratory was found in compliance with applicable CLIA regulations (42 CFR Part 493, Requirements for Laboratories) for the specialties/subspecialties for which it was surveyed. STANDARD LEVEL DEFICIENCIES were cited.
D5217	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1)</p> <p>At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory's policies/procedures, twice annual test accuracy verification studies, annual test volumes and staff interview, the laboratory failed to document twice annual test accuracy verification for two of two events in 2024. Findings included: 1. Review of laboratory's policy "Proficiency Testing Mohs Micrographic Surgery Skin Specimens" (approved by Laboratory Director in 2021) revealed: "Semi-annually, the tech or Risk Manager will send two cases containing the original slides, label it with only the surgical case number, and send it out for a microscopic examination by a Board Certified(sic) Dermatopathologist." 2. Review of laboratory's twice annual test accuracy verification studies revealed the last verification study was documented in November 2023. There was no documentation of the semi-annual verification of test accuracy in 2024. 3. Review of laboratory's submitted annual test volume revealed the laboratory performed two MOHS procedures in 2024. 4. In an interview on 05/30/2025 at 0950 hours in the laboratory, the facility's Medical Assistant (as indicated on submitted Survey Entrance/Exit Conference document) confirmed the findings.</p>