

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D2189526	(X3) Date Survey Completed 04/01/2025
Name of Provider or Supplier Orlando Dermatology Clinic Llc	Street Address, City, State 1040 Lake Sumter Landing, The Villages, FL	
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 CLIA recertification survey was conducted at Orlando Dermatology LLC on 04/01/2025. The laboratory is not in compliance with 42 CFR Part 493, Requirements for Laboratories. The following is a description of the standard level deficiencies:
D5473	<p>CONTROL PROCEDURES CFR(s): 493.1256(e)(2)(g)</p> <p>(e)(2) Each day of use (unless otherwise specified in this subpart), test staining materials for intended reactivity to ensure predictable staining characteristics. Control materials for both positive and negative reactivity must be included, as appropriate.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview it was determined the laboratory failed to verify the Hematoxylin and Eosin (H&E) test staining materials for intended reactivity for two of two year (2023-2024). Findings include: 1. Record review of 2023-2024 H&E Quality Control (QC) records revealed no documentation the H&E test staining materials for intended reactivity was reviewed by the Laboratory Director (LD). 2. The CMS 209 Laboratory Personnel Record signed by the Laboratory Director on 04/01/2025 listed the LD as the only Testing Person(TP) qualified to verify H & E staining materials for reactivity. 3. Interview with TP#A on 04/01/2025 at 4:15 PM confirmed the LD did not sign off on daily QC log.</p>