

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D2000049	(X3) Date Survey Completed 06/26/2025
Name of Provider or Supplier Naples Dermatology Pa	Street Address, City, State 4951 Tamiami Trl N Ste 112, Naples, 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 NAPLES DERMATOLOGY PA on June 26, 2025. The laboratory was not in compliance with 42 CFR Part 493, Requirements for Laboratories. The following is a description of the standard level deficiencies:
D3011	<p>FACILITIES CFR(s): 493.1101(d)</p> <p>Safety procedures must be established, accessible, and observed to ensure protection from physical, chemical, biochemical, and electrical hazards, and biohazardous materials.</p> <p>This STANDARD is not met as evidenced by: Based on lack of records and staff interview, the laboratory failed to monitor the Xylene and 10% Neutral Buffered Formalin exposure limits for at least 2 out of 2 years reviewed. Findings included: 1-Review of Procedure Manual signed by the laboratory director on 06/03/2025, revealed that the laboratory failed to include a policy to implement the monitoring of the staff exposure to Xylene and 10% Neutral Buffered Formalin used in the laboratory. 2-Review of specimen policy revealed that the specimens are received in a 10 % Neutral Buffered Formalin bottle. 3-Review of Thermo Shandon Scientific Excelsior ES tissue processor procedure revealed that they used the 10 % Formalin solution in the first two stations for tissue dehydration and Xylene in the ten, eleven and twelve station for clearing. Review of the Hematoxylin and Eosin stain process revealed that the laboratory used Xylene. -Review of Safety Data Sheet of brands used by the laboratory for: a) 10% Neutral Buffered Formalin from Anapath, Statlab and Mercedes Scientific revealed that the OSHA Permissible Limits (PELS) were 0.75 ppm (parts per million). b) Xylene from Anapath and Statlab revealed that the OSHA PEL was 100 ppm. During an interview on 06/26/2025 at 11: 35 AM, Testing Personnel #2 confirmed that the laboratory failed to effectively monitor the Xylene and 10% Neutral Buffered Formalin exposure.</p>