

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D2139264	(X3) Date Survey Completed 08/05/2025
Name of Provider or Supplier Aqua Dermatology Of Florida Pa	Street Address, City, State 3140 Us Hwy 27 S, Avon Park, 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 Aqua Dermatology of Florida PA on 08/04/2025 - 08/05/2025. The laboratory is not in compliance with 42 CFR Part 493, Requirements for Laboratories. The following is a description of the standard level deficiency:
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 observation, review of reagent safety data sheets, and staff interview, the laboratory failed to ensure protection from chemical hazards for 2 of 2 years (08/2023 - 08/2025). Findings included: 1. Observations were performed during a tour of the laboratory with the Clinical Laboratory Specialist (CLS) on 08/04/2025 at 10:25 a.m. Xylene substitute reagent was observed stored in the flammable cabinet. The CLS stated the reagent present (Reagent #A), when completely used up, would be supplied by a different manufacturer (Reagent #B). No fume hood was observed above the staining station. 2. The manufacturer Safety Data Sheet (SDS) for Reagent #A currently used by the laboratory, with a revision date of 12/08/2024 was reviewed. The SDS stated "Harmful if inhaled" and "Use only outdoors or in a well-ventilated area." The manufacturer SDS for Reagent #B with a revision date of 10/05/2015 was reviewed. The SDS showed "...where exposure levels are not known wear approved respiratory protection," and "IF INHALED: Remove person to fresh air." 3. On 08/04/2025 at 12:40 p.m., the CLS confirmed the lab did not monitor air quality/exposure to reagent and did not have a fume hood to mitigate exposure to the Xylene substitute reagent.</p>