

<p>Statement of Deficiencies</p>	<p>(X1) Provider/Supplier/CLIA Identification Number</p> <p>10D0962536</p>	<p>(X3) Date Survey Completed</p> <p>05/20/2025</p>
<p>Name of Provider or Supplier</p> <p>Aqua Dermatology Of Florida Pa</p>	<p>Street Address, City, State</p> <p>8340 Lakewood Ranch Blvd Suite 260, Bradenton, FL</p>	
<p>For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.</p>		

(X4) ID Prefix Tag	Summary Statement of Deficiencies
<p>D0000</p>	<p>An announced CLIA recertification survey was conducted at Aqua Dermatology of Florida PA on 05/20/2025. The laboratory is not in compliance with 42 CFR Part 493, Requirements for Laboratories. The following is a description of the standard level deficiency:</p>
<p>D3011</p>	<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 reviewed (05/2023-05/2025). Findings included: Observations were performed during a tour of the lab on 05/20/2025 at 9:45 a.m. with the Director of Clinical Laboratory Operations (DCLO). Xylene Substitute reagent was stored in the flammable cabinet. The DCLO 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. The manufacturer safety data sheet (SDS) for the Xylene Substitute (Reagent #A) currently used by the laboratory, with a revision date of 08-Dec-2015 was reviewed. The SDS stated "Harmful if inhaled" and "Use only outdoors or in a well-ventilated area." The manufacturer SDS for the Xylene Substitute (Reagent #B) with a revision date of 10/05/2016, had a pictogram of a head wearing a respirator. The SDS stated "...where exposure levels are not known wear approved respiratory protection," and "IF INHALED: Remove person to fresh air..." On 05/20/2025 at 10:15 a.m., the DCLO stated the lab does not monitor air quality/exposure to reagent and does not have a fume hood to mitigate exposure to the Xylene Substitute reagent.</p>