

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D2213205	(X3) Date Survey Completed 07/02/2025
Name of Provider or Supplier Luminary Dermatology Pa	Street Address, City, State 2032 Hawthorne St, Sarasota, 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 Luminary Dermatology PA on 7/1-7/2/2025. The laboratory is not in compliance with 42 CFR Part 493, Requirements for Laboratories. The following is a description of the standard level deficiencies:
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 records, and interview, the laboratory failed to ensure protection from chemical hazards for seventeen months (2/2024 to 7/2025). Findings included; 1. During a tour of the laboratory on 7/1/25 at 11:11 a.m., Xylene Substitute was observed stored in the safety cabinet. The primary container for the Xylene Substitute label included the hazard sign for respiratory and stated under precautionary statements-"Avoid breathing vapors". A laminated sheet was observed in the safety cabinet with the stored reagents which included hazards for each reagent, for Xylene Substitute it stated "Danger! Harmful if inhaled." The manufacturer safety data sheet (SDS), with a revision date of 10/05/2016, for the Xylene Substitute stated to use only outdoors or in a well ventilated area. 2. The histology tech confirmed on 7/1/25 at 11:11 a.m., the laboratory did not have a fume hood to mitigate exposure to harmful chemical fumes from the Xylene Substitute. The histology tech stated on 7/1/25 at 11:30 a.m., the laboratory had moved to the current location 2/2024 (specific date unknown) and had not installed a fume hood.</p>
D6093	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5)</p>

(e)(5) Ensure that the quality control and quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur;

This STANDARD is not met as evidenced by:

Based on review of the policy and procedure manual, review of records, and interview, the Laboratory Director failed to establish a comprehensive quality assessment program to encompass all aspects of laboratory services from 5/5/23 to 7/1/25. Findings included: 1. The laboratory Policy and Procedure manual was reviewed and approved by the Laboratory Director 1/20/2025. There was no policy for a quality assessment program approved by the Laboratory Director included in the Policy and Procedure manual. 2. The last documented quality assurance performed by the laboratory was prior to the last survey on 5/5/23. 3. The Laboratory Director on 7/02/2025 at 8:00 a.m. confirmed the above.