

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D2251108	(X3) Date Survey Completed 08/27/2026
Name of Provider or Supplier Luminary Dermatology, Pa	Street Address, City, State 8740 N Kendall Drive Suite 101, Miami, 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 OF MIAMI LLC on August 27, 2026. The laboratory is not in compliance with 42 CFR Part 493, Requirement for Laboratories. The following Condition was cited: D5200 493.1230 - Condition: General Laboratory Systems
D3011	FACILITIES CFR(s): 493.1101(d) Safety procedures must be established, accessible, and observed to ensure protection from physical, chemical, biochemical, and electrical hazards, and biohazardous materials. This STANDARD is not met as evidenced by: Based on observation, review of Safety Data Sheet (SDS) and staff interview, the laboratory failed to ensure protection from chemicals hazards used for Histopathology testing of Hematoxylin and Eosin (H&E) stain from 11/04/2024 to 08/27/2026. Findings included: 1-During a tour of the laboratory on 08/27/2026 at 12:20 PM, no fume hood observed to provide protection from respiratory chemical hazards of the reagents used for H&E stain. 2-The SDS sheets for Xylene Substitute, Reagent Alcohol 100%, Reagent Alcohol 95%, all included hazard statements regarding inhalation precautions. 3-During an interview on 08/27/2026 at 12:55 PM, Testing Personnel #2 confirmed that there was no hood or any other method to ensure respiratory protections from chemical hazards used for H&E staining.
D5200	GENERAL LABORATORY SYSTEMS CFR(s): 493.1230 Each laboratory that performs nonwaived testing must meet the applicable general laboratory systems requirements in 493.1231 through 493.1236, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7),

that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the general laboratory systems and correct identified problems specified in 493.1239 for each specialty and subspecialty of testing performed.

This CONDITION is not met as evidenced by:

Based on record review and staff interview, the laboratory failed to verify accuracy of the reading and interpretation of the hematoxylin and Eosin (H&E) stain at least annually for 2025. (See D5217).

D5217

EVALUATION OF PROFICIENCY TESTING PERFORMANCE

CFR(s): 493.1236(c)(1)

At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.

This STANDARD is not met as evidenced by:

Based on record review and staff interview, the laboratory failed to ensure the twice a year accuracy verification for histopathology testing for one out of two years reviewed. This is a repeated deficiency from the recertification survey on 11/04/2024. Findings included: 1-Review of Test Menu listed on form CMS-116 signed by Laboratory Director (LD) on 08/27/2026 revealed that the laboratory performed the Histological interpretation for Hematoxylin and Eosin (H&E) in frozen sections. 2- Review of Plan of Correction (POC) signed by the LD on 11/08/2024, revealed that the laboratory implemented a Policy "Proficiency Testing Protocol" that stated the following: "Bi-annually Mohs specimen slides will be randomly chosen for review by a Credentialed Mohs Surgeon to ensure the diagnosis, sectioning quality, staining quality and presence/absence of tumor." 3- Review of the laboratory peer review records, revealed the following: a-On 01/23/2025 the laboratory sent one case for review and the reviewer signed in 02/09/2025. No other case sent for review in 2025. b-On 01/23/2025 the laboratory sent one case for review and the reviewer signed on 02/09/2026. c-On 08/06/2026, the laboratory sent one case for review and the reviewer signed on 08/12/2026. 4-During an interview on 08/27/2026 at 01:35 PM, the Laboratory Consultant confirmed that the laboratory failed to do accuracy verification histopathology twice a year during 2025.