

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D2251108	(X3) Date Survey Completed 11/04/2024
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	A recertification survey was conducted on October 23, 2024 to November 4th, 2024. LUMINARY DERMATOLOGY, PA clinical laboratory was not in compliance with 42 CFR 493, requirements for clinical laboratories. The following Condition was cited: D6076 - Laboratory Director 493.1441
D5217	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to verify the accuracy of Histopathology testing at least twice annually for 1 (2023) out of 2 years (2022-2024) reviewed. Findings included: 1. Personnel records reviewed revealed that in the Histopathology section there was one testing person (laboratory director TP1) as per CMS 209 Form. 2. Review of Subpart I, 42 CFR Part 493.901 through 493.959 revealed that there was no approved proficiency testing programs for the interpretation of stained tissues. 3. Review of the Quality Assurance (QA) peer review found that peer review for Histopathology was done for the laboratory director (LD#1) in October of 2022. The laboratory did not provide Histopathology peer review record for the year 2023 during which the laboratory had a change of directorship to LD#2 (04/01/2023) and LD#3 (09/20/2023). 4. During interview on 10/23/2024 at 1:30 PM the Mohs Technician confirmed there was no QA peer review documentation for the year 2023.</p>
D5429	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1)</p> <p>For unmodified manufacturer's equipment, instruments, or test systems, the laboratory</p>

must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.

This STANDARD is not met as evidenced by:

Based on record review and staff interview, the laboratory failed to perform maintenance as specified by the manufacturer for 2 out of 2 years (2023 and 2024) reviewed for the Cryostat Avantik. Findings included: 1- Preventive maintenance records for Cryostat Avantik, serial number 43363, were not provided for the year 2023 and 2024. 2- Review of the Manufacturer instructions # 387 779 - Maintenance section 5-3 Cleaning and care of the microtome revealed the following note: For the examination and readjustment of the microtome a routine maintenance should be performed by trained service technician once a year. 3- Interview on 10/23/2024 at 1:00pm with laboratory technician stated that maintenance records would be sent via email by 10/25/2024. Records were not received.

D6076

LABORATORY DIRECTOR

CFR(s): 493.1441

The laboratory must have a director who meets the qualification requirements of 493.1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart.

This CONDITION is not met as evidenced by:

Based on record review and staff interview, the laboratory failed to ensure that the laboratory director met qualifications in 2023. Refer to D6078

D6078

LABORATORY DIRECTOR QUALIFICATIONS

CFR(s): 493.1443

The laboratory director must be qualified to manage and direct the laboratory personnel and performance of high complexity tests and must be eligible to be an operator of a laboratory within the requirements of subpart R. (a) The laboratory director must possess a current license as a laboratory director issued by the State in which the laboratory is located, if such licensing is required; and (b) The laboratory director must-- (b)(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (b)(1)(ii) Be certified in anatomic or clinical pathology, or both, by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (b)(2) Be a doctor of medicine, a doctor of osteopathy or doctor of podiatric medicine licensed to practice medicine, osteopathy or podiatry in the State in which the laboratory is located; and (b)(2)(i) Have at least one year of laboratory training during medical residency (for example, physicians certified either in hematology or hematology and medical oncology by the American Board of Internal Medicine); or (b)(2)(ii) Have at least 2 years of experience directing or supervising high complexity testing; or (b)(3) Hold an earned doctoral degree in a chemical, physical, biological or clinical laboratory science from an accredited institution and-- (b)(3)(i) Be certified and continue to be certified by a board approved by HHS; or (b)(3)(ii) Before February 24, 2003, must have served or be serving as director of a laboratory performing high complexity testing and must have at least-- (b)(3)(ii)(A) Two years of laboratory training or experience, or both; and (b)(3)(ii)(B) Two years of laboratory experience

directing or supervising high complexity testing. (b)(4) Be serving as a laboratory director and must have previously qualified or could have qualified as a laboratory director under regulations at 42 CFR 493.1415, published March 14, 1990 at 55 FR 9538, on or before February 28, 1992; or (b)(5) On or before February 28, 1992, be qualified under State law to direct a laboratory in the State in which the laboratory is located; or (b)(6) For the subspecialty of oral pathology, be certified by the American Board of Oral Pathology, American Board of Pathology, the American Osteopathic Board of Pathology, or possess qualifications that are equivalent to those required for certification.

This STANDARD is not met as evidenced by:

Based on record review and staff interview, the laboratory failed to ensure that the laboratory director met qualifications for high complexity Histopathology for 1 (2023) out of 2 years (2022-2024) reviewed. Findings Included: 1- The laboratory had a change of directorship from Laboratory Director (LD#1) whose resignation letter was effective 01/30/2023 to LD#2 (CLIA application 04/01/2023-not finalized), and LD#3 (CLIA application 09/20/2023-not finalized). 2- Review of the laboratory policies and procedures revealed it was signed by the LD#1 on October 13, 2022, and LD#3 on 10/23/2024. There were no new signatures recorded for 2023 by any laboratory director. 3- The laboratory received an Omission Notice dated 07/24/2023 regarding application #294544 requesting the director's copy of board of certification certificate (s). The laboratory failed to provide documentation for LD#2 qualifications, therefore the change of LD was not performed. 4- During phone interview on 11/01/2024 at 2:50PM, the technician revealed that LD#2 decided to step down before the paperwork was completed because she was moving to another institution.

D6106

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1445(e)(14)

The laboratory director must ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process.

This STANDARD is not met as evidenced by:

Based on record review and interview with laboratory staff, the laboratory failed to approve and sign the laboratory policies and procedures for 1 (2023) out of 2 years (2022-2024) reviewed. Findings included: 1- Review of the Policies and Procedures for the laboratory showed that signature and approval of the laboratory directors (LD) were missing from 2023. 2- Review of CMS 116 change of Directorship requests for LD2 (04/01/2023) and LD3 (09/20/2023) confirmed the change during 2023. Refer to D6078. 3- Telephone interview with Mohs Technician on 10/31/2024 at 1:40PM, revealed that the laboratory had changed laboratory director from LD1, LD2 and LD3 all during the year 2023.