

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D2174136	(X3) Date Survey Completed 12/14/2021
Name of Provider or Supplier Luminary Dermatology, Pa	Street Address, City, State 1550 E Venice Ave, Venice, 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 12/14/21. The laboratory is not in compliance with 42 CFR Part 493, Requirements for Laboratories. The following is a description of the standard level deficiencies:
D5433	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(1)</p> <p>For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must establish a maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. The laboratory must perform and document the maintenance activities specified in paragraph (b)(1)(i) of this section.</p> <p>This STANDARD is not met as evidenced by: Based on observation, record review, and interview with the Operations Manager, the laboratory failed to perform yearly preventive maintenance on the Microm cryostat used for histopathology testing for 1 (2020) of 2 years reviewed (2019-2021). The findings included: On 12/14/21 at 10:55 a.m., the Microm cryostat was observed to have a preventive maintenance sticker that indicated the preventive maintenance was due 12/20. Review of the equipment maintenance records for 2019 - 2021 revealed no documentation of annual preventive maintenance on the Microm cryostat. Review of the laboratory's undated procedure titled "Cryostat Maintenance" revealed "Routine Maintenance Procedure... 3. Schedule preventive maintenance once a year..." On 12/14 /21 at 11:40 a.m., the Operations Manager stated she did not believe that periodic maintenance had been done because she could not find the invoice for the service.</p>