

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  10D0276503	<b>(X3) Date Survey Completed</b>  09/26/2023
<b>Name of Provider or Supplier</b>  Advanced Dermatology And	<b>Street Address, City, State</b>  3755 7th Terrace, Vero Beach, FL	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D0000</b>	Initial certification survey was conducted from 8/16/2023 to 9/26/2023. Advance Dermatology and Cosmetic Surgery clinical laboratory was not in compliance with 42 CFR Part 493, requirements for clinical laboratories.
<b>D5217</b>	<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 interview, the laboratory failed to perform biannual verification of accuracy for Potassium Hydroxide (KOH) testing in 2022. Findings included: Review of Biannual KOH and /or Scabies competency and Proficiency Testing for Laboratory personnel disclosed verification of accuracy for KOH testing was done by moderate testing person A on 4/6/2022. There was no other verification of KOH testing in 2022. Review of Verification of PPM Test Results read, "Procedure: Parasitology and KOH twice a year, the testing personnel will select a patient from who to collect a specimen for competency and proficiency testing." Review of KOH Log showed KOH testing was performed from 2/2/2022 to 6/3/2022. On 8/16/2023 at 1:00 PM, the laboratory location Manager confirmed KOH verification was not performed for a second time in 2022.</p>
<b>D5413</b>	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p> <p>The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if</p>

applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.

This STANDARD is not met as evidenced by:

Based on record review and interview, the laboratory failed to record laboratory temperature and humidity for 3 out of 5 patients review for Mohs micrographic surgery (MOHS) testing. Findings Included: Review of Mohs patient testing disclosed the following: a.) patient #1 was tested for MOHS on 9/21/2022. b.) patient#2 was tested for MOHS on 6/22/2023. c.) patient#3 was tested for MOHS on 5/25/2023. Review of Laboratory Temp/Humidity log displayed temperature and humidity was not noted for the dates 9/21/2022, 6/22/2023 or 5/25/2023. Review of Linisat Linear Stainer manual read, "Temperature (operating limits): +5 Celsius (C) to +40 C (+41 Fahrenheit (F) to 104 F) Temperature (storage): -25 C to +55 C (-13 F to 131 F) +70C (158 F) for short exposure Relative Humidity (RH): Max 80% RH up to 31 C Decreasing linearly to 50% RH at 40 C On 8/16/2023 at 2:18 PM, the laboratory's location Manager confirmed that temperature and humidity were not recorded for dates that 3 out of 5 patients were tested for MOHS testing.

**D5415**

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT  
CFR(s): 493.1252(c)

Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use.

This STANDARD is not met as evidenced by:

Based on observation, record review, and interview, the laboratory failed to label the Thermo Scientific Linistat to identify what reagents were in use for MOHS testing. Findings included: On 8/16/2023 at 11:31 AM, a Thermo Scientific Linistat sat on the counter with unlabeled containers to identify what reagents were in use for MOHS testing. Review of MOHS Quality Assurance Manual disclosed no policy for labeling reagents. On 8/16/2023 at 1:51 PM, the laboratory's location Manager confirmed Linistat containers were not labeled to identify reagents.