

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  10D2092107	<b>(X3) Date Survey Completed</b>  05/18/2022
<b>Name of Provider or Supplier</b>  Advanced Dermatology And Cosmetic Surgery	<b>Street Address, City, State</b>  600 W Plymouth Ave, Deland, 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>	An announced CLIA initial survey was conducted at Advanced Dermatology & Cosmetic Surgery on 5/18/2022. The laboratory is not in compliance with 42 CFR Part 493, Requirements for 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 staff interview, the laboratory failed to send Mohs histopathology patient slides for peer review more than once annually in 2021. Findings include: The record review of documented peer review for 2021 showed that patient slides for Deland office were reviewed on 7/13/21. Documentation showing peer review for the surgeon's Ormond Beach (10D1029479) location was included dated 12/2021. The laboratory did not have a second peer review documented for the Deland office. During an interview with the Mohs technician on 5/18/22 at 10:30am, it was stated that they were told by their supervisor that they could combine peer review documentation since the surgeon performs the testing at multiple offices. She confirmed individual office peer review for 2021 had not been performed. .</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 applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity.</p>

(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 identify that the room temperature and humidity range established to run the Avantik QS12 cryostat and Microm HM520 cryostat was outside the required operating temperature range for five of five months reviewed. (January - May 2022). The findings include: The instruction manual for the Avantik QS12 cryostat states under Technical Specifications the "Temperature (Operating limits) are 5C to +35C (+41F to +95F) at a max. Relative humidity of 60%. Temperature (Recommended Operation) +15C to +30C (+59F to +86F) NOTE: Performance may deteriorate when operated outside of this range." The instruction manual for the Microm HM520 cryostat states "Operating Conditions: +5C up to +35C (at a max. rel. humidity of 60%)". The review of the document titled "Advanced Dermatology Laboratory Temp/Humidity Log" showed the acceptable room temperature range is "36-105 degrees" with no indication of Fahrenheit or Celsius. The acceptable range for lab humidity on the form is documented as "0%-87%". During the interview with the Office Manager on 5/18/22 at 10:30am, it was confirmed the laboratory was not monitoring room temperature and humidity based on manufacturers instructions. .

**D5781**

**CORRECTIVE ACTIONS**

CFR(s): 493.1282(b)(1)

(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population.

This STANDARD is not met as evidenced by:

Based on record review and staff interview, the facility failed to document corrective action when the Cryostat temperature was out of range for 5 of 5 months reviewed (January 2022 - May 2022). The findings include: Record review of the "Cryostat Temperature" logs showed the acceptable "Normal Range" temperature is " -18C to -27 Celsius (C) ". The following dates had temperatures out of range for "Cryostat #1 with no corrective action documented: 1. January 18, 2022: documented temperature of "-36C" 2. January 25, 2022: documented temperature of "-38C" 3. February 1, 2022: documented temperature of "-38C" 4. February 8, 2022: documented temperature of "-38C" 5. February 15, 2022: documented temperature of "-38C" 6. February 22, 2022: documented temperature of "-38C" 7. March 1, 2022: documented temperature of "-38C" 8. March 8, 2022: documented temperature of "-38C" 9. March 22, 2022: documented temperature of "-38C" 10. March 29, 2022: documented temperature of "-38C" 11. April 5, 2022: documented temperature of "-38C" 12. April 12, 2022: documented temperature of "-38C" 13. April 26, 2022: documented temperature of "-38C" 14. May 3, 2022: documented temperature of "-38C" 15. May 10, 2022: documented temperature of "-39C" 16. May 17, 2022: documented

temperature of "-38C" The review of facility policy titled "Quality Control Maintenance" last revised on 2/2/2021 states "Cryostat Temperature: 1. The temperature of the cryostat must be recorded and initialed each day of use. 2. If the temperature is found to be out of range, i.e. -27 degrees C to -10 degrees C., the temperature is returned to the acceptable range." Interview with the Office Manager on 5/18/22 at 10:15am confirmed no corrective action was documented for the out of range temperature for the Cryostat used to cut patient tissue specimens for slide preparation and staining. It was stated that Cryostat #1 was known to have issues of being too cold, however no documentation was available showing Cryostat #1 was not used to cut patient tissue specimens on the 16 days listed. .