

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D2077522	(X3) Date Survey Completed 03/04/2022
Name of Provider or Supplier Lisa D Zack Md Pa D/B/A	Street Address, City, State 19910 S Tamiami Trl Ste B, Estero, 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 recertification survey was conducted 2/21/22 through 3/4/22 at Lisa D Zack MD PA D/B/A Florida Coastal Dermatology, a clinical laboratory in Estero, Florida. Lisa D Zack MD PA D/B/A Florida Coastal Dermatology is not in compliance with Code of Federal Regulations (CFR) 42, Part 493, Laboratory Requirements.
D5413	<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. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview with lab personnel, the laboratory failed to include an acceptable humidity range on log sheets and failed to document the correct acceptable temperature for the laboratory. The findings included: Record review of the "Temperature Quality Control Log" revealed no acceptable humidity range for the years 2020, 2021 and the first two months of 2022. It was also discovered that the laboratory room temperature was incorrectly written as: (-) 24 degrees Celsius (+/- 5 degrees) for the years 2020, 2021, and the first two months of 2022. Interview with laboratory personnel on 2/21/2022 at approximately 3:50 p.m., confirmed that the acceptable humidity range was missing from the log sheets. On 3/04/2022, through email, it was confirmed that the laboratory room temperature was incorrect. Laboratory personnel wrote: "The range should be 68-80 degrees Fahrenheit".</p>

D5429

MAINTENANCE AND FUNCTION CHECKS

CFR(s): 493.1254(a)(1)

For unmodified manufacturer's equipment, instruments, or test systems, the laboratory 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 interview with lab personnel, the laboratory failed to perform annual maintenance on their Leica and Olympus microscopes. Findings include: Record review revealed no microscope maintenance records for the Leica and Olympus microscopes. Interview with lab personnel on 2/21/2022 at 3:45 p.m., confirmed no annual maintenance had been performed on the Leica and Olympus microscopes.