

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D2158758	(X3) Date Survey Completed 06/04/2021
Name of Provider or Supplier Dermatology Associates Of The Palm Beaches, Pllc	Street Address, City, State 2160 Duck Slough Blvd - Ste 103, Trinity, 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	AMENDED REPORT: Issued 06/14/2021 An announced CLIA initial certification survey was conducted at Dermatology Associates of the Palm Beaches on 06/04/2021. The laboratory is not in compliance with 42 CFR Part 493, Requirements for Laboratories. The following is a description of the standard level deficiencies:
D3011	<p>FACILITIES CFR(s): 493.1101(d)</p> <p>Safety procedures must be established, accessible, and observed to ensure protection from physical, chemical, biochemical, and electrical hazards, and biohazardous materials.</p> <p>This STANDARD is not met as evidenced by: Based on observation, record review and interview the laboratory failed to store and dispose of 100% Reagent Alcohol and Eosin per the manufacturers' instructions (MI) since testing began. Findings Included: During a tour of the laboratory on 06/04/2021 at 10:15 AM, 100% Reagent Alcohol was observed being stored under a table and Eosin was observed being stored in a desk drawer. Review of the MI revealed that the 100% Reagent Alcohol should be stored "in an approved flammable liquids storage area." It also stated to "Dispose of contents/container to an approved waste disposal plant." Review of the MI for the Eosin revealed that it was a Class 3 fire hazard. It also stated "Do not dispose of in drains." Interview on 06/04/21 at 10:30 AM with the Practice Administrator confirmed that the laboratory did not have a flammable cabinet for storage. She also confirmed that the 100% Reagent Alcohol and Eosin was being disposed of down the drain.</p>
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</p>

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.

This STANDARD is not met as evidenced by:

Based on record review and interview the laboratory failed to record the cryostat temperatures for 3 (02/12/21, 03/26/21, and 05/28/21) out of 3 days (02/12/21, 03/26/21, and 05/28/21) tested. Findings Included: Review of the cryostat temperature logs revealed no temperatures were only recorded. No other logs with temperatures for the cryostat were found. A review of quality control logs revealed that testing occurred on 02/12/21, 03/26/21, and 05/28/21. Interview on 06/04/21 at 12:00 PM with the Practice Administrator confirmed that the cryostat temperatures were not recorded on the 3 testing days.