Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D2152572	09/20/2022
Name of Provider or Supplier	**Street Address, City, State**	
Delray Dermatology Llc	550 Se 6th Ave Suite 100, Delray Beach, 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 on 9/20/22 at Delray Dermatology LLC, a clinical laboratory in Delray Beach, Florida. Delray Dermatology LLC is not in compliance with Code of Federal Regulations (CFR) 42, Part 493, Laboratory Requirements.
D3011	FACILITIES CFR(s): 493.1101(d) Safety procedures must be established, accessible, and observed to ensure protection from physical, chemical, biochemical, and electrical hazards, and biohazardous materials. This STANDARD is not met as evidenced by: Based on observation, record review, and interview the laboratory failed to store 100% Reagent alcohol according to the manufacturer's instructions. The findings included: During a tour of the laboratory on 09/20/22 at 1:00 p.m., 4 boxes that contained 4-1 gallon bottles of 100% Reagent alcohol was seen stacked up beside of the cryostat. Also observed was a 5 gallon and 10 gallon waste container in front of the boxes of 100% Reagent alcohol that contained 100% Reagent alcohol. Review of Mercedes Scientific safety data sheet for 100% Reagent alcohol revealed that the storage conditions was to "Store in an approved Flammable Liquids storage area." Interview on 09/20/22 the Laboratory Manager confirmed that the 100% Reagent alcohol was stored outside of the flammable cabinet.
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) 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.

	This STANDARD is not met as evidenced by: Based on record review and interview the laboratory failed to verify the accuracy of testing at least twice a year for 1 (2021) out of 2 years (2020-2022) reviewed for Histopathology. The findings included: Review of Quality Assurance (QA) peer reviews from 07/2020 to 09/2022 revealed that there was no documentation of any performed in 2021. Interview on 09/20/22 at 1:00 PM the Laboratory Manager confirmed that there were no peer reviews to verify the accuracy of testing in 2021.