Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D2106853	10/27/2021
Name of Provider or Supplier	**Street Address, City, State**	
Coastal Dermatology Laboratory	4400 Hwy 20e Ste 410, Niceville, 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	A recertification survey was conducted on October 27, 2021. Coastal Dermatology Laboratory clinical laboratory was not in compliance with 42 CFR 493, Requirements for Clinical Laboratories.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on record review and interview with the Chief Executive Officer, the laboratory failed to document annual competencies for one of three Histotechnologists (Testing Personnel B) for three of three years reviewed. Findings included: Personnel records from May of 2019 until October of 2021 were reviewed and no competency documentation was found for the years 2019, 2020, or 2021 for Testing Personnel B. Interview with the Chief Executive Officer on 10/27/2021 at 0925 confirmed that no competencies had been conducted for Testing Personnel B for the years 2019, 2020, and 2021.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) 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. This STANDARD is not met as evidenced by: Based on record review and interview with Testing Personnel A, the laboratory failed to establish and document an acceptable reference range for room air temperature and humidity and did not document Paraffin temperature. Findings included: Record review of temperature logs for November 2019, May 2020, and September 2021 did not have a documented acceptable reference range for room air temperature or humidity. Record review of the VIP Tissue-Tek Processor revealed the Paraffin temperature was not documented for the entire month of May 2020 and the entire month of September 2020. Interview with Testing Personnel A on 10/27/2021 at 10: 30 AM, confirmed that the acceptable reference range for room air temperature and humidity were not established and documented, and the temperature had not been taken for Paraffin for the months of May 2020 and September 2020.