Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D2042968	03/07/2022
Name of Provider or Supplier	**Street Address, City, State**	
Suncoast Skin Solutions Inc	4601 Military Trl Ste 203, Jupiter, 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 3/7/22 at Skin Cancer Care Specialist LLC, a clinical laboratory in Boynton Beach, Florida. Skin Cancer Care Specialist LLC, is not in compliance with Code of Federal Regulations (CFR) 42, Part 493, Laboratory Requirements. The following is a description of the noncompliance.
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 and interview with the Histotechnologist, the laboratory failed to dispose of 100% Reagent Alcohol, Methanol anhydrous, Isopropyl alcohol, and 10% Formalin Fixative for 2 out of 2 (2020-2022) years reviewed. Findings Included: Observation of reagents in the flammable cabinet on 03/07/2022 at 1:00 p.m. revealed the labels on the 100% Reagent Alcohol, Methanol anhydrous, Isopropyl alcohol, and 10% Formalin Fixative stated the contents/container be disposed of at an approved waste disposal plant. (Photographic evidence obtained). On 3/7/22 at 1:20 p.m., the Histotechnologist stated that alcohol was disposed of down the drain of the sink with copious amounts of water and the 10% Formalin was neutralized and then poured down the drain..
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 the Histotechnologist, the laboratory failed to record the room temperature and room humidity every day that testing was performed from January 15, 2020 to the day of survey, 03/07/2022. Findings Included: Review of the Avantik cryostat instrument manual revealed that the operating temperature range should be 15 degrees Celsius to 30 degrees Celsius and the maximum humidity should be 60%. Review of the Thermo Scientific Tissue Embedding Center Microm EC 350 Instruction Manual revealed the operating temperature range should be 5 to 40 degrees Celsius and the maximum humidity of 60%. On 3/7/22 at 2:30 p.m., the Histotechnologist stated she did not know the laboratory was supposed to be documenting room temperature and humidity.