Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D2144520	05/02/2022
Name of Provider or Supplier	**Street Address, City, State**	
Riverchase Dermatology	200 Glades Road #1, Boca Raton, 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 conducted on 05/02/2022 found the RIVERCHASE DERMATOLOGY clinical laboratory not in compliance with 42 CFR Part 493, Requirements for Laboratories.
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 staff interview, the laboratory failed to document cryostat temperature, room temperature and percentage humidity requirement for the Leica CM 1850 UV cryostat for one out of 50 testing dates from 01/01/2020 to 05/02/2022 and the laboratory failed to follow manufacturer instructions requirement to ensure optimal operation for the Leica CM 1850 UV cryostat and performed testing while humidity was out of the acceptable range for 24 out of 50 testing dates from 01/01 /2020 to 05/02/2022. The findings include: Review of Leica CM 1850 UV cryostat manual revealed a requirement for optimal operation a range of cryostat temperature of -15 to -25 degrees Celsius (C) for skin without fat and -25 to -35 C for Skin with fat, room temperature below 35 C and Humidity must not exceed 60 %. A review of temperature logs for 2020 and 2021, revealed the following: -The laboratory failed to document the cryostat temperature, room temperature and room humidity on 1 testing day (08/26/2020) out of 50 testing days from 01/01/2020 to 05/02/2022. -The laboratory failed to follow manufacturer's instructions to operate the cryostat in

	humidity conditions below 60 % for 24 testing dates: 09/23/2020, 09/30/2020, 10/07 /2020, 10/14/2020, 11/04/2020, 11/11/2020, 11/18/2020, 12/09/2020, 12/16/2020, 12 /30/2020, 01/06/2021, 01/13/2021, 02/17/2021,03/10/2021, 04/07/2021, 04/21/2021, 04/28/2021, 07/21/2021, 09/22/2021, 10/20/2021. During an interview on 05/02/2022, the Mohs Manager confirmed that the laboratory failed to document the temperature requirements for 08/16/2020 and that the humidity was outside of the instrument requirement for the days listed above.