Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D1080066	09/30/2024
Name of Provider or Supplier	**Street Address, City, State**	
Dermaclinique	510 E Druid Road Suite A, Clearwater, 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 CLIA recertification survey was conducted at Dermaclinique on 09/30/2024. The laboratory is not in compliance with 42 CFR Part 493, Requirements for Laboratories. The following is a description of the standard level deficiencies:
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 review of manufacturer's instructions, lack of documentation, and interview with the Laboratory Director, the laboratory failed to document the humidity to ensure the correct operating conditions for the cryostat for two out of two years reviewed (2023 - 2024). Findings included: Review of the "Leica CM 1850 UV Instructions for Use" for the cryostat revealed "...air humidity lower than 60%" No documentation of humidity from January 1, 2023 to September 17, 2024 could be provided. On 09/30/2024 at 10:35 AM, the Laboratory Director confirmed that the humidity had not been documented. .
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at

	least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on record review and interview with the Laboratory Director, the laboratory failed to document daily and weekly maintenance for the Leica CM 1850 UV cryostat used for preparing tissue for histopathology slides two out of two years (2023-2024) reviewed. Findings included: Review of the "Leica CM 1850 UV Instructions for Use" revealed "Clean the instrument every day" and "Once a week apply a drop of oil....and Lubricate the specimen cylinder." Review of the laboratory's procedure "Daily Routine" revealed "12. At the end of the day, clean cryostat according to maintenance log, and document." Review of the "Moh's [sic] microscopic oriented histographic surgery, Q/A [Quality Assurance] and Q/C [Quality Control] Checklist" logs revealed that the "Cryostat Clean/Oil" maintenance had not been documented from January 1, 2023 to September 17, 2024. On 09/30/2024 at 10:25 AM, the Laboratory Director stated the "Cryostat Clean/Oil" maintenance was not documented from January 1, 2023 to September 17, 2024.
D5433	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(1) For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must establish a maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. The laboratory must perform and document the maintenance activities specified in paragraph (b)(1)(i) of this section. This STANDARD is not met as evidenced by: Based on record review and interview with the Laboratory Director, the laboratory failed to document the maintenance of the microscope used in the histopathology laboratory that performs Hematoxylin and Eosin slide stains for two out of two years (2023-2024) reviewed. Findings included: Record review of the laboratory's procedure "Microscope Maintenance" revealed "5. Document daily..." Record review of the "Mohs [sic] Q/A [Quality Assurance] and Q/C [Quality Control] Checklist" logs showed the "Microscope" maintenance had not been documented from January 1, 2023 to September 2024. On 09/30/2024 at 10:25 AM, the Laboratory Director confirmed the microscope maintenance was not documented.
D5609	HISTOPATHOLOGY CFR(s): 493.1273(e)(f) (e) The laboratory must use acceptable terminology of a recognized system of disease nomenclature in reporting results. (f) The laboratory must document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to document quality control information including the lot numbers, expiration dates, and open dates for all reagents used for the Hematoxylin and Eosin stain for two out of two years (2023 -

	2024) reviewed. Findings included: Review of the "Quality Control Policies and Documentation" revealed "2. Reagent lot numbers and expiration dates will be recorded." Review of the laboratory's quality control records revealed there was no documentation for reagents. On 09/30/2024 at 10:30 AM, the Laboratory Director confirmed the laboratory was not documenting lot numbers, expiration dates, and open dates for all reagents used for the Hematoxylin and Eosin stain.