Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	07D2205250	04/18/2023
Name of Provider or Supplier	**Street Address, City, State**	
Modern Dermatology	1032 Post Rd East, Westport, CT	

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
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 staff interview, the laboratory failed to verify the accuracy of the microscopic histopathology results for the Micrographically Oriented Histographic Surgery (MOHS) procedure twice annually for 2021 and 2022. Findings include: 1. Record review on 4/18/2023 of the 'Proficiency Testing MOHS Micrographic surgery Skin specimens' procedure revealed that the laboratory instituted an External Quality control program indicating semi-annually, 2 cases containing the original slides will be send out for microscopic examination by a Board Certified Pathologist. The reports will be attached and placed in "Proficiency Testing" located in quality control manual. 2. Record review on 4/18/2023 of the quality control manual revealed lack of documentation of the proficiency testing performed twice annually for 2021 and 2022. 3. Staff interview with testing personnel #1 on 4/18 /2023 at 10:40 AM confirmed the laboratory failed to follow the above procedure. He /she further mentioned, it was her/his understanding that performing the monthly audit of a random specimen covered the proficiency testing protocol.
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 staff interview, the laboratory failed to follow their established policy and procedure for maintenance and function checks on the laboratory microscope in the specialty of histopathology. Findings include: 1. Record review on 4/18/2023 of the dermatology "Microscope" procedure manual revealed the annual Preventative Maintenance (PM) to be performed and documented annually. 2. Record review on 4/18/2023 of the 2022 and 2023 maintenance records revealed lack of documentation of the PM records for the microscope in use. 3. Staff interview with testing personnel #1 on 4/18/2023 at 11:10 AM confirmed the above findings.