Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	21D2279618	10/08/2025
Name of Provider or Supplier	**Street Address, City, State**	
Modern Dermatology Of Maryland Llc	2568a Riva Road Suite 102, Annapolis, MD	

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
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) (d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory procedure for performing the dermatophyte test media cultures for patient specimens was not signed as reviewed and approved by the laboratory director. This was confirmed during interview with the office manager on 10/8/2025 at 11:00 am.
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) (a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory did not perform testing using the dermatophyte test media (DTM) as instructed by the manufacturer. Findings: 1. The manufacturer states that the laboratory interpret DTM cultures for no longer than 14 days and false positive results may occur after 14 days. 2. Patient #1 DTM culture was inoculated on 7/1/2025, and the date the culture was interpreted was on 9/8/2025 (as documented on the intermediate test record log) and Patient #2 DTM was inoculated on 6/24/2025, and the date the culture was interpreted was on 9/8/2025 (as documented on the intermediate tes record log). 3. Both patient test results for DTM

	were interpreted over the two week time period as instructed by the manufacturer. 4. This was confirmed during interview with the laboratory director on 10/8/2025 at 11: 30 am.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) (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: (b)(1) Water quality. (b)(2) Temperature. (b)(3) Humidity. (b)(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, the laboratory did not document the initials of the person recording the room and refrigerator temperatures. Findings: 1. The laboratory keeps separate logs for the room temperature readings and the refrigerator temperature readings to ensure that the dermatophyte test media cultures are incubated at the acceptable room temperature and that the media is stored properly. 2. The individual temperature readings for both the room and refrigerator for the year 2024 did not have the initials of the staff member(s) who recorded the temperature readings. 3. This was confirmed during interview with the office manager on 10/8/2025 at 11:30 am.
D5433	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(1) (b)(1)(i) 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. (b)(1)(ii) 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, the laboratory did not provide reliable documentation for microscope preventive maintenance. Findings: 1. The 2024 microscope daily preventive maintenance was missing documentation for the months of November and December and the 2025 preventive maintenance record was completed for all the months of the year, including November and December 2025. 2. The microscope daily preventive maintenance records for the year 2024 were missing the initials of the staff who performed the preventive maintenance. 3. This was confirmed during interview with the office manager on 10/8/25 at 11:00 am.
D5787	TEST RECORDS CFR(s): 493.1283(a) (a) The laboratory must maintain an information or record system that includes the following: (a)(1) The positive identification of the specimen. (a)(2) The date and time of specimen receipt into the laboratory. (a)(3) The condition and disposition of

	specimens that do not meet the laboratory's criteria for specimen acceptability. (a)(4) The records and dates of all specimen testing, including the identity of the personnel who performed the test(s). This STANDARD is not met as evidenced by: Based on record review and interview with the laboratory director, the dates entered onto the patient log and the chart record for interpretation of patient cultures using the dermatophyte test media (DTM) did not agree. Findings: 1. The DTM for Patient #1 was inoculated on 7/1/2025, the intermediate record showed that the DTM was interpreted on 9/8/2025, but the patient chart stated that the DTM interpretation was made in 13 days. 2. The DTM for Patient #2 was inoculated on 6/24/25, the intermediate record showed that the DTM was interpreted on 9/8/2025, but the patient chart did not have a date that the DTM was interpreted. 3. This was confirmed during interview with the laboratory director on 10/10/8/2025 at 11:30 am.