

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 49D0694874	(X3) Date Survey Completed 08/24/2023
Name of Provider or Supplier Dermatology Plc	Street Address, City, State 320 Winding River Lane - Suite 301, Charlottesville, VA	
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 the Dermatology PLC on 08/24/23 by the Virginia Department of Health's Office of Licensure and Certification. The laboratory was surveyed under 42 CFR part 493 CLIA Requirements. Specific deficiencies cited are as follows:
D5411	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on the review of daily patient test log, manufacturer's instructions for use, patient medical note, lack of documentation, and interview, the laboratory failed to follow manufacturer's instructions for culture incubation time for one of two patient fungal culture results performed in 2022. Findings include: 1. Review of the daily patient test logs revealed two dermatophyte cultures performed on two patients in the 2022. Patient #1 collection and inoculation date on 01/31/22 and a "Date Read" on 05/25/22. 115 days between date of inoculation and date of reading the culture for results. 2. Review of the manufacturer's instructions for use for the Accuderm AcuDTM Dermatophyte test medium revealed the following statement, "Reading should be made within fourteen days. Interpretation of the test is questionable after fourteen days due to the possibility of false positives". 3. Review of the patients' medical notes in the Modernizing Medicine electronic health record revealed a note of the DTM culture read on 04/20/22 and lacked documentation of a reading of the DTM culture at the required 14-day incubation time period. 4. In an interview with the office manager and primary nurse on 08/24/23 at 10:15 AM, the office manager stated</p>

that they "felt the culture was read at the 14-day incubation time period but the reviewing clinician failed to record the finding." 5. In an exit interview with the same staff at 10:25 AM the findings were confirmed.