Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	49D0694874	05/23/2019
Name of Provider or Supplier	**Street Address, City, State**	
Dermatology Plc	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 May 23, 2019 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	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(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 tour of testing area, policy and procedure (P&P) review, manufacturer's package insert (PI) and phone conference with manufacturer, patient test log and interview with testing physician and office manager, the laboratory failed to follow manufacturer's instructions for incubation timeframe of the Dermatophyte Test Medium (DTM) for one (1) of 1 patient on the date of survey on May 23, 2019. Findings include: 1. Tour of the testing area for the DTM culture revealed 1 patient sample (patient 1) incubating at room temperature. The collection date on the vial was April 10, 2019. The inspector requested to review results for patient 1 in the Modernizing Medicine electronic medical records. There was no result for patient 1. 2. Review of the P&P revealed the following statements (approved by the lab director on 8/25/2015): "Dermatology PLC Laboratory Manual" III. Dermatophyte Culture- E. Interpretation of Results- A failure to recover mycelial growth and appropriate color change by two weeks is generally considered a negative test result." 3. Review of the Acu-Derm PI and call to the manufacturer at approximately 10:47 AM revealed that the incubation timeframe is 14 days after inoculation. Color change can be assessed

	from as early as 24 hours and up to 14 days. "Interpretation of test is questionable after 14 days due to the possibility of false positives". The representative from Acu-Derm stated: "we will not support any interpretation of fungal readings after 14 days." 4. An interview with the testing physician and office manager at approximately 11:15 AM confirmed that patient 1 sample exceeded the manufacturer defined 14 days incubation timeframe, inoculated on April 10, 2019 and no interpretation of color change or growth at the date of survey (43 days of incubation).