

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  49D0893619	<b>(X3) Date Survey Completed</b>  02/03/2021
<b>Name of Provider or Supplier</b>  Pariser Dermatology Specialists	<b>Street Address, City, State</b>  11842 Rock Landing Rd, Ste 120, Newport News, VA	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D0000</b>	<p>An announced CLIA recertification survey was conducted at Pariser Dermatology Specialists on February 2-3, 2021 by the Virginia Department of Health's Office of Licensure and Certification. The remote survey included record review on 02/02/2021 with virtual interviews and tour on 02/03/21. The laboratory was surveyed under 42 CFR part 493 CLIA Regulations. Specific deficiency cited is as follows:</p>
<b>D5411</b>	<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 a review of the policy manual, manufacturer's package insert, patient logs, and an interview, the laboratory failed to follow the manufacturer's instructions for culture incubation time for nine (9) of eighty-nine (89) patient culture results reviewed between January 16, 2019 to January 29, 2021. Findings include: 1. Review of the laboratory's Dermatology Procedure Manual revealed a Fungal Culture policy that outlined that the laboratory utilizes Accuderm's ACU-DTM Dermatophyte Test Medium to detect dermatophytes from patient cutaneous sources. The policy stated "The culture must be interpreted by a provider within 10-14 days of inoculation. Any culture that has not been interpreted within 14 days must be repeated". 2. The Accuderm's manufacturer's package insert defined the patient incubation period of up to fourteen (14) days and instructions to disregard any color change in the medium after the 14 days of incubation. The package insert instructions stated "Reading should be made within fourteen days. Color interpretation of the test is questionable after fourteen days due to the possibility of false positives". 3. The inspector selected 89</p>

random patient case numbers from the DTM patient logs (timeframe of 01/16/19 to 01/29/21) for review. The review of the selected patient DTM culture results revealed the following case number entries having incubation periods outside the protocol of 14 days: Case number 460110 on 02/19/19 recorded as being read on 2/18/19; Case number 3185730 on 02/01/19 incubated fifteen (15) days; Case number 2929550 on 04/03/19 incubated 15 days; Case number 3164430 on 05/28/19 incubated sixteen (16) days; Case number 2974830 on 10/21/19 incubated twenty-one (21) days; Case number 2098480 on 10/31/19 recorded as being read on 10/15/19; Case number 1872800 on 10/31/19 recorded as being read on 10/15/19; Case number 1017820 on 10/31/19 recorded as being read on 10/15/19; Case number 2855960 on 1/12/21 incubated 15 days; a total of 9 patient results were recorded outside of the manufacturer's recommended incubation time. 4. In an exit interview with the operation manager on 02/03/21 at approximately 11:30 AM, the above findings were confirmed.