Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	49D0918172	09/22/2022
Name of Provider or Supplier	**Street Address, City, State**	
Pariser Dermatology Specialists, Ltd	207 Bulifants Blvd - Suite C, Williamsburg, 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 Pariser Dermatology Specialists, LTD -Williamsburg on September 22, 2022 by the Virginia Department of Health's Office of Licensure and Certification. The inspector noted that the laboratory performs SARS-CoV-2 (COVID-19) testing and was in compliance with the applicable COVID-19 reporting requirements. The laboratory was surveyed under 42 CFR part 493 CLIA Requirements. Specific deficiency cited is 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 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 six (6) of fifty-four (54) patient culture results reviewed between December 15, 2020 to the date of the survey on September 22, 2022. 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 "Exam the culture for up to 14 days for color change and/or growth". 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. Interpretation of the test is questionable after fourteen days due to the possibility of false positives". 3. The inspector selected 54 random patient case numbers from the DTM patient logs

	(timeframe of 12/15/20 to 09/22/22) 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 2984330 on 12/16/20 incubated eighteen (18) days; Case number 3513570 on 04/28/21 incubated twenty-three days; Case number 1142540 on 11/19/21 incubated 18 days; Case number 1541910 on 01/04 /22 recorded as result read retroactively on 01/04/21; Case number 3631140 on 01/04 /22 recorded as being read retroactively on 01/04/21; Case number 3982860 on 07/12 /22 incubated sixteen days; a total of 6 patient results were recorded outside of the manufacturer's recommended incubation time. 4. An exit interview with the operation managers on 09/22/22 at approximately 1:00 PM confirmed the above findings.