Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	49D2022169	04/21/2022
Name of Provider or Supplier	**Street Address, City, State**	
Pariser Dermatology Specialists	3907 Bridge Road, Suite 200, Suffolk, 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 (Suffolk) on April 21, 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 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 a review of policy/procedures, manufacturer's package insert, patient logs, and an interview, the laboratory failed to follow the manufacturer's instructions for culture incubation period for twelve (12) of forty (40) randomly selected patient Fungal culture results reviewed from 2020 and 2021 logsheets. Findings include: 1. Review of the laboratory's Dermatology Procedure Manual revealed a Fungal Culture policy that outlined that the laboratory utilizes ACU-DTM Dermatophyte Test Medium to detect dermatophytes from patient cutaneous sources. The policy stated "Examine the culture for up to 14 days." 2. The DTM 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 (14) days due to the possibility of false positives". 3. The inspector selected 40 random patient account numbers from the 2020 and 2021 DTM patient logs for review. Review of the

	randomly selected patient DTM culture results revealed the following entries having incubation periods exceeding fourteen (14) days: 2011090 on 08/11/20 incubated twenty (20) days; 707500 on 09/16/20 incubated fifteen (15) days; 3581790 on 12/21 /20 incubated fifteen (15) days; 3207690 on 01/06/21 incubated fifteen (15) days; 3804070 on 03/03/21 incubated twenty-one (21) days; 2163880 on 04/06/21 incubated twenty (20) days; 2497160 on 04/08/21 incubated eighteen (18) days; 3080910 on 04 /09/21 incubated seventeen (17) days; 3837130 on 04/09/21 incubated seventeen (17) days; 2934690 on 11/10/21 incubated nineteen (19) days-culture A; 2934690 on 11/10 /21 incubated nineteen (19) days-culture B; 933510 on 11/10/21 incubated eighteen (18) days; a total of 12 of 40 patient results reviewed were recorded outside of the manufacturer's recommended incubation time. 4. An exit interview with the office Clinical Operations Manager on 4/21/22 at approximately 3:30 PM, confirmed the above findings.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on a tour, review of policy and procedure manual, patient test logs, and interviews, the laboratory failed to ensure that their Potassium Hydroxide (KOH) 10% and fungal stain reagent, stored in the nursing station microscopy area, were within the manufacturer's stated expiration dates for two (2) of 2 lot numbers of reagents while reporting thirty-two (32) patient Tissue Fungal Exam KOH results from September 30, 2021 to the date of the survey on April 21, 2022. Findings include: 1. During a laboratory tour of the nursing station microscopy area on 4/21/22 at approximately 2:15 PM, the inspector noted the following 2 expired reagents: Medical Chemical Company Potassium Hydroxide 10%, Lot Number 0084-00 (manufacturer's printed expiration date 09/30/2021); HealthLink Fungal Black E Stain, Lot Number 9296 (manufacturer's printed expiration date 10/23/2021). The laboratory inspector noted substantial particulate matter afloat in the reagent bottles and inquired if the expired KOH and fungal stain reagents were being used for patient testing. The operations manager and lead nurse confirmed with statement: "Yes, they are still being used. We will reorder today". 2. Review of the laboratory's policy and procedure manual revealed a Potassium Hydroxide (KOH) Examination procedure that included a Reagents Storage, Use, and Handling protocol that stated: "Do not use the KOH 10% and KOH with Chlorazol Black E reagents after expiration date". 3. Review of the laboratory's Tissue Exam Fungal KOH test logs revealed 32 patient results were reported while utilizing the expired reagents (timeframe 9/30/21 to 4/21 /22). 4. An exit interview with the office Clinical Operations Manager on 4/21/22 at approximately 3:30 PM, confirmed the above findings.