

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 49D2072133	(X3) Date Survey Completed 03/04/2021
Name of Provider or Supplier Pariser Dermatology Specialists, Ltd	Street Address, City, State 510 Independence Parkway Suite 600, Chesapeake, 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 on March 4, 2021 by the Virginia Department of Health's Office of Licensure and Certification. The laboratory was surveyed under 42 CFR part 493 CLIA Regulations. Specific deficiency cited is as follows:
D5413	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p> <p>The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.</p> <p>This STANDARD is not met as evidenced by: Based on interviews, review of room temperature records, patient logs, and manufacturer's Dermatophyte Test Medium (DTM) package insert, the laboratory failed to record/monitor daily room temperature of the cabinet area utilized to incubate DTM culture medium on eight (8) days while reporting ten (10) patient results during the twenty-four (24) months reviewed. Findings include: 1. During the entrance interview on 3/4/21, the inspector noted that in the survey timeframe (February 2019 to the date of the survey) the laboratory performed DTM fungal cultures and confirmed with the office manager that the cultures were incubated in the nursing cabinet area. 2. The inspector reviewed the DTM room temperature records for the timeframe outlined above, and noted that the laboratory failed to record the incubation room temperature on the following 8 days: 11/1-11, 2019 and 9/29/20. The inspector requested to review the temperature recordings for the dates outlined above.</p>

The office manager confirmed on 3/4/21 at approximately 10:30 AM, that the laboratory failed to perform the temperature checks. 3. Review of the patient DTM logs for the 8 days outlined above revealed the following 10 patient cultures (by chart number) were incubated during the lapse in temperature monitoring: 3375370, 3397590, 2154060 (thumb and hand sample), 3410790, 3084220, 3655270, 3664950, 1659170, and 3647770. 4. Review of the Accuderm package insert revealed the following instructions: Incubate media at room temperature (15-30 C), aerobically, for up to fourteen days. Organisms differ in their requirements for humidity, temperature, atmosphere, and duration of incubation. The requirements must be observed in order to successfully culture the desired organism; variations of intended results may be due to improper specimen exposure to temperatures. 5. In an exit interview with the operation manager on 03/04/21 at approximately 3:30 PM, the above findings were confirmed.