

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D0615781	(X3) Date Survey Completed 09/23/2026
Name of Provider or Supplier Dermatology Consultants Of Sacramento, Amc	Street Address, City, State 5340 Elvas Ave Ste 600, Sacramento, CA	
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
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) (b) 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: (b)(1) Water quality. (b)(2) Temperature. (b)(3) Humidity. (b)(4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on observation of Fungal Cultures in progress, review of Hardy Diagnostics Mycobiotic Agar (Catalog # L45) "Instructions For Use", the lack of thermometers and laboratory records, and interview with Laboratory Assistant - 1 and the Laboratory Director, it was determined that the laboratory failed to define and monitor Temperatures for storing uninoculated agar slants and for incubating inoculated Fungal Cultres for dermatophytes and yeast. Findings included: 1. The laboratory had a partial box of tubes of Mycobiotic Agar in 10 mL slants on an open shelf. 2. On the same open shelf, the laboratory had a partial rack of inoculated fungal cultures incubating for dermatophytes and yeast. 3. The manufacturer's instructions for Storage stated to store the L45 tubes of agar slants upon receipt at 2-30 degrees C. 4. The instructions for "Procedure" specified inoculating the specimen onto the agar medium, followed by the "Method of Use" to incubate the tube at 25 - 30 degrees C. 5. No theremometer was observed next to the box of L45 tubes. No thermometer was observed in the rack with the cultures that were incubating. 6. From the laboratory's Fungal Culture Log Book, 3 records from 2025, and 5 records from 2026, were selected for review, as follows: Date Specimen ----- 5/01/25 R great toe 7/22/25 L 3rd toe nail 9/25/25 R great toe 3/04/26 R 3rd finger 5/08/26

	fingernails 5/26/26 L thumbnail 6/23/26 R great toe nail 8/31/26 R great toe 7. For 7 out of 7 fungal cultures, the laboratory failed to have records documenting the temperature for each day of incubation. 8. When interviewed, Laboratory Assistant -1 and the Laboratory Director affirmed (9/23/26 at 12:30 PM) the aforementioned findings and that the laboratory hadn't been monitoring Temperatures for storage or for incubating. .
D6010	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(2) (e)(2) Ensure that the physical plant and environmental conditions of the laboratory are appropriate for the testing performed and This STANDARD is not met as evidenced by: Based on the findings and citation of noncompliance, the Laboratory Director is herein cited for deficient practice in ensuring that the temperatures were monitored and documented for storing Mycobiotic Agar and incubating Fungal Cultures. See D5413.