

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D2165560	(X3) Date Survey Completed 01/31/2025
Name of Provider or Supplier Advanced Dermatology Center	Street Address, City, State 1624 W Olive Ave Ste B, Burbank, 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
D3011	<p>FACILITIES CFR(s): 493.1101(d)</p> <p>Safety procedures must be established, accessible, and observed to ensure protection from physical, chemical, biochemical, and electrical hazards, and biohazardous materials.</p> <p>This STANDARD is not met as evidenced by: Based on the surveyor's observation during the laboratory tour and interview with office manager (OM), it was determined that the laboratory failed to have an established, accessible, and observed safety procedures to ensure protection from any physical, chemical, biochemical, electrical hazards, and biohazardous materials. The findings include: 1. Based on the laboratory tour on January 31, 2025, at approximately 12:40 p.m., the surveyor observed: a. No eye wash station or portable bottles was found within the testing area where biohazardous materials were processed. b. One out of three fire extinguishers in the facility was missed during the last annual service. Two were last serviced on July 14, 2024, while the one at the laboratory was last serviced on June 30, 2023. 2. The OM affirmed by interview on January 31, 2025, at approximately 12:40 p.m. that the laboratory lacked an eye wash and that the fire extinguisher was missed from the last annual service as mentioned in statement #1. 3. Based on the laboratory's annual testing volume declaration submitted at the time of the survey, the laboratory processed and reported approximately 100 patient test samples for Dermatopathology.</p>
D5435	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(2)</p> <p>(b)(2)(i) Define a function check protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (b)(2)(ii) Perform and document the function checks, including</p>

background or baseline checks, specified in paragraph (b)(2)(i) of this section. Function checks must be within the laboratory's established limits before patient testing is conducted.

This STANDARD is not met as evidenced by:

Based on a review of the laboratory's preventive maintenance (PM) documentation, five (5) randomly selected patient test records, and an interview with the office manager (OM), it was determined that the laboratory failed to ensure performed tests and function checks were documented properly prior to patient testing. The findings include: 1. Based on the review of the 5 patient test records, no corrective action was found for the two out of 5 records that were discrepant in documentation. Thus, the accuracy and quality of patient reports cannot be ascertained. a. Patient AR serviced on July 10, 2023, had a missing entry for cryostat temperature and PM. b. Patient GT serviced on March 11, 2024, was recorded under March 8, 2024, in the staining quality control assessment PM log. 2. The OM affirmed by interview at approximately 1:45 p.m. on January 31, 2025, that the laboratory missed checking the log sheet when quality assessment was performed as mentioned in statement #1. 3. Based on the annual testing declaration form submitted at the time of the survey, the laboratory performed and reported approximately 100 patient tests for Dermatopathology, including the time the missing and incorrect entries for PM occurred. Thus, the quality and accuracy of patient reports cannot be assured.

D6084

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1445(e)(2)

provide a safe environment in which employees are protected from physical, chemical, and biological hazards;

This STANDARD is not met as evidenced by:

Based on the surveyor's findings during the tour, the laboratory director is herein cited for the deficient practice in failure to provide and overall administration of the laboratory to ensure a safe environment in which personnel are protected from physical, chemical, biochemical, electrical hazards, and biohazardous materials. Findings include: See D3011.

D6097

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1445(e)(7)

(e)(7) that patient test results are reported only when the system is functioning properly;

This STANDARD is not met as evidenced by:

Based on the surveyor's review of the laboratory's preventive maintenance documentation, randomly chosen patient test records from 8/13/2023 to 10/14/2024, and interview with the office manager, it was determined that the laboratory director failed to ensure that equipment was maintained and properly recorded prior to patient testing. See D5435.