

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D1007383	(X3) Date Survey Completed 04/22/2025
Name of Provider or Supplier Dermatology And Laser Center Of San Diego	Street Address, City, State 319 F St Ste 102, Chula Vista, 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 review of 2022-2025 laboratory records for Mohs procedures, observed in the laboratory: one 1-Gallon size container of Alcohol 100% [Avantik Batch #240927-B104434, Expiration date 10/17/27] and two 1-Gallon-size containers of Acetone [Lot #2220720, Expiration date 7/31/25], the lack of a Flammables Storage Cabinet, and interview with a laboratory person, it was determined the laboratory failed to establish Safety procedures for storing flammable materials in a Flammables Storage Cabinet to ensure protection from chemical fire hazards. Findings included: 1. Laboratory records for 2022-2025 documented that glass slides from Mohs procedures were processed and stained onsite in the laboratory, requiring the use of 100% Alcohol and Acetone. 2. Three gallon-sized containers of 100% Alcohol and Acetone were seen stored in a regular cupboard under the countertop. 3. The laboratory assistant affirmed (4/22/25 at 3:00 PM) the aforementioned finding; and thus, the laboratory failed to establish fire safety procedures for storing Alcohol, Acetone and any other flammable materials. 4. The safety and protection of laboratory personnel from chemical fires was not assured. .</p>
D5217	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1)</p> <p>At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.</p>

This STANDARD is not met as evidenced by:

Based on review of 2022-2024 laboratory records for Biopsy pathology reports and records for Mohs procedures, the lack of records verifying the accuracy of reported Biopsy pathologies and the final stage of Mohs procedures, and interview with laboratory personnel, it was determined the laboratory failed to verify the accuracy of testing. Findings included :

1. The Laboratory Personnel Report (form CMS209, 4/09/25) included four Medical Doctors as testing personnel in Dermatopathology /Histopathology. The CLIA Application (form CMS116, 4/09/25) specified Histopathology testing in Biopsies and Mohs.
2. BIOPSIES
 - a. The Pathology Reports for 2022-2024 documented Testing Person-3 reported Biopsy pathology results.
 - b. The laboratory was unable to provide for this CLIA survey records verifying the accuracy of Biopsy pathologies reported in 2022.
 - c. A laboratory assistant affirmed (4/22/25 at 3:30 pm) the aforementioned findings.
 - d. And thus, the accuracy of reporting Biopsies in 2022 was not assured during this CLIA survey. Cases randomly selected for peer review and corrective action to verify accuracy for 2022 are, as follows: Date Slide ID Pathology collected reported ----- 1/05/22 W22 - 024 EIC/epidermal cyst 9/07/22 W22 - 2711 Solar elastosis 12/20/22 W22 - 3956A Squamous Cell Carcinoma
3. MOHS PROCEDURES
 - a. Mohs records for 2022-2024 documented Final Stage of clearing tumor by Testing Person-2.
 - b. The laboratory was unable to provide for this CLIA survey records verifying the accuracy of Testing Personnel to clear tumors in 2022, 2023, and 2024; the laboratory was unable to provide a written Policy and Procedure for verifying and documenting the accuracy of each Testing Person performing Mohs procedures, at least twice within each calendar year.
 - c. A laboratory assistant affirmed (4/22/25 at 3:30 pm) the aforementioned findings.
 - d. And thus, the accuracy of Mohs procedures to clear tumors was not assured during this CLIA survey. Cases randomly selected for peer review and corrective action to verify accuracy are, as follows: Date Mohs ID Final stage ----- 2/14/22 M22-140 (not provided) 10/31/22 M22 -346 I 2/01/23 M23 -35 I 5/03/23 M23 -139 I 12/27/23 M23 -382 II 4/22/24 M24 -132 II 8/27/24 M24 -196 II 12/19/24 M24 -173 I
4. The laboratory performed and reported 4,000 histopathology tests annually, including Biopsies and Mohs (CMS116, CLIA Application, 4/09/25). .