

<p>Statement of Deficiencies</p>	<p>(X1) Provider/Supplier/CLIA Identification Number</p> <p>10D2043829</p>	<p>(X3) Date Survey Completed</p> <p>03/06/2026</p>
<p>Name of Provider or Supplier</p> <p>Florida Center For Dermatology Laboratory</p>	<p>Street Address, City, State</p> <p>1301 Plantation Island Dr South Ste 106b, Saint Augustine, FL</p>	
<p>For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.</p>		

<p>(X4) ID Prefix Tag</p>	<p>Summary Statement of Deficiencies</p>
<p>D0000</p>	<p>An announced CLIA recertification survey was conducted at Florida Center for Dermatology Laboratory on 3/6/2026. The laboratory is not in compliance with 42 CFR Part 493, Requirements for Laboratories. The following is a description of the standard level deficiencies:</p>
<p>D3011</p>	<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 observation and interview, the laboratory failed to ensure protection from chemical hazards by storing bulk flammable reagents in a non-rated laboratory cabinet rather than a designated flammable storage cabinet, and by failing to maintain a sanitary storage environment for 20 of 20 1-gallon reagent containers observed. Findings include: During a tour of the laboratory at 11:15 am on 3/6/2026, the following bulk flammable reagents were observed stored inside a standard wood-laminate laboratory cabinet located under a counter: Fifteen (15) 1-gallon bottles of 95% reagent grade alcohol; Two (2) 1-gallon bottles of Eosin Y solution; and Three (3) 1-gallon bottles of 100% alcohol. The manufacturer's labels on the bulk alcohol and Eosin Y containers displayed the "flame" pictogram, indicating the contents were highly flammable and required appropriate hazardous material storage. Observation of the interior of the storage cabinet on 3/6/2026 revealed a lack of sanitary maintenance and protection from contamination. The cabinet shelves were heavily soiled with various colored stains, and the reagent bottles were observed sitting in pools of pink and purple liquids. In an interview on 3/6/2026 at 12:05 PM, the Mohs technician confirmed the laboratory possessed a designated flammable storage cabinet; however,</p>

further confirmed that the standard laboratory cabinet was also being used to store these bulk flammable chemicals.

D5203

SPECIMEN IDENTIFICATION AND INTEGRITY

CFR(s): 493.1232

The laboratory must establish and follow written policies and procedures that ensure positive identification and optimum integrity of a patient's specimen from the time of collection or receipt of the specimen through completion of testing and reporting of results.

This STANDARD is not met as evidenced by:

Based on record review and interview, the laboratory failed to ensure the positive identification of patient specimens from the time of receipt through the reporting of results for 88 of 88 Mohs surgery cases reviewed between July 17, 2025, and August 1, 2025, where the accession numbers recorded in the laboratory's primary log did not match the accession numbers documented on the corresponding surgical maps and patient slides. Findings include: A review of the laboratory's 2025 "MOHS LOG" revealed extensive manual edits and renumbering of patient case numbers for five testing days. The original accession numbers were crossed out or obscured, and a new numerical sequence was substituted. The number of patient records renumbered on the primary log included: 7/17/2025: 20 patient records; 7/29/2025: 17 patient records; 7/30/2025: 13 patient records; 7/31/2025: 19 patient records; and 8/1/2025: 19 patient records. A comparative review of the primary log pages against the clinical surgical maps and prepared patient slides for these 88 cases confirmed that the accession numbers did not match. For example, for Patient #1 on 7/17/2025, the Mohs slide and Mohs Map identified the specimen with Accession #FCDm25-1291, but the primary laboratory log showed that the entry for Accession #1291 had been crossed out and edited to Case #1301. A review of the remaining 87 Mohs surgery cases (Patients #2 through #88) revealed similar discrepancies where the renumbered Case #s in the primary log did not match the original accession numbers preserved on the surgical maps and slides. In an interview on 3/6/2026 at 12:30 PM, the Mohs Technician confirmed that the accession numbers on the surgical maps and slides for those specific dates in 2025 did not match the renumbered entries in the primary log. During an interview with the Laboratory Director via phone on 3/6/2026 at 12:35 PM, he acknowledged the identification error and stated that the laboratory would implement corrective actions to remediate the discrepancy and prevent recurrence.